

Adverse Events
Safety Analysis Set

Placebo								
Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b		
01-701-1015 / 63/W/F	GASTROINTESTINAL DISORDERS/ DIARRHOEA/ DIARRHOEA	- (-) / Ongoing (.)	Mild	1	Remote	-		
01-701-1015 / 63/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE ERYTHEMA/ APPLICATION SITE ERYTHEMA	- (-) / Ongoing (.)	Mild	3	Probable	-		
01-701-1015 / 63/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-		
01-701-1023 / 64/W/M	CARDIAC DISORDERS/ ATRIOVENTRICULAR BLOCK SECOND DEGREE/ ATRIOVENTRICULAR BLOCK SECOND DEGREE	- (-) / Ongoing (.)	Mild	3	Possible	-		
01-701-1023 / 64/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Mild	3	Possible	-		
01-701-1023 / 64/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Moderate	3	Probable	-		
01-701-1023 / 64/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Mild	1	Possible	-		
01-701-1047 / 85/W/F	GASTROINTESTINAL DISORDERS/ HIATUS HERNIA/ HIATUS HERNIA	- (-) / Ongoing (.)	Moderate	3	None	-		

Copyright © DH

Adverse Events
Safety Analysis Set

Placebo								
Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b		
01-701-1047 / 85/W/F	GASTROINTESTINAL DISORDERS/ HIATUS HERNIA/ HIATUS HERNIA	- (-) / Ongoing (.)	Moderate	1	None	-		
01-701-1047 / 85/W/F	CARDIAC DISORDERS/ BUNDLE BRANCH BLOCK LEFT/ BUNDLE BRANCH BLOCK LEFT	- (-) / Ongoing (.)	Mild	3	None	-		
01-701-1047 / 85/W/F	INFECTIONS AND INFESTATIONS/ UPPER RESPIRATORY TRACT INFECTION/ UPPER RESPIRATORY TRACT INFECTION	- (-) / Ongoing (.)	Mild	3	None	-		
01-701-1118 / 52/W/M	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS/ COUGH/ COUGH	- (-) / Ongoing (.)	Mild	3	None	-		
01-701-1130 / 84/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ PYREXIA/ PYREXIA	- (-) / Ongoing (.)	Mild	1	None	-		
01-701-1130 / 84/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Mild	3	Remote	-		
01-701-1130 / 84/W/M	INFECTIONS AND INFESTATIONS/ URINARY TRACT INFECTION/ URINARY TRACT INFECTION	- (-) / Ongoing (.)	Mild	3	None	-		
01-701-1130 / 84/W/M	INFECTIONS AND INFESTATIONS/ URINARY TRACT INFECTION/ URINARY TRACT INFECTION	- (-) / Ongoing (.)	Mild	1	None	-		

Copyright © DH

Adverse Events
Safety Analysis Set

Placebo								
Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day)/ Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b		
01-701-1130 / 84/W/M	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS/ NASAL CONGESTION/ NASAL CONGESTION	- (-)/ Ongoing (.)	Mild	3	Remote	-		
01-701-1130 / 84/W/M	EYE DISORDERS/ EYE ALLERGY/ EYE ALLERGY	- (-)/ Ongoing (.)	Mild	1	None	-		
01-701-1130 / 84/W/M	EYE DISORDERS/ EYE PRURITUS/ EYE PRURITUS	- (-)/ Ongoing (.)	Mild	3	Remote	-		
01-701-1130 / 84/W/M	EYE DISORDERS/ EYE SWELLING/ EYE SWELLING	- (-)/ Ongoing (.)	Mild	1	None	-		
01-701-1153 / 79/W/F	METABOLISM AND NUTRITION DISORDERS/ INCREASED APPETITE/ INCREASED APPETITE	- (-)/ Ongoing (.)	Mild	3	Possible	-		
01-701-1153 / 79/W/F	METABOLISM AND NUTRITION DISORDERS/ INCREASED APPETITE/ INCREASED APPETITE	- (-)/ Ongoing (.)	Mild	1	Possible	-		
01-701-1203 / 81/B/F	SURGICAL AND MEDICAL PROCEDURES/ EYE LASER SURGERY/ EYE LASER SURGERY	- (-)/ Ongoing (.)	Mild	1	None	-		
01-701-1363 / 81/B/F	GASTROINTESTINAL DISORDERS/ NAUSEA/ NAUSEA	- (-)/ Ongoing (.)	Mild	1	Remote	-		

Copyright © DH

Adverse Events
Safety Analysis Set

Placebo								
Subject ID/ Age/Race/Se x	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b		
01-701-1363 / 81/B/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-		
01-701-1363 / 81/B/F	MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS/ BACK PAIN/ BACK PAIN	- (-) / Ongoing (.)	Mild	3	None	-		
01-701-1363 / 81/B/F	MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS/ BACK PAIN/ BACK PAIN	- (-) / Ongoing (.)	Mild	1	None	-		
01-701-1363 / 81/B/F	NERVOUS SYSTEM DISORDERS/ HEADACHE/ HEADACHE	- (-) / Ongoing (.)	Moderate	3	Possible	-		
01-701-1363 / 81/B/F	NERVOUS SYSTEM DISORDERS/ HEADACHE/ HEADACHE	- (-) / Ongoing (.)	Mild	3	Possible	-		
01-701-1387 / 87/W/F	GASTROINTESTINAL DISORDERS/ DIARRHOEA/ DIARRHOEA	- (-) / Ongoing (.)	Mild	1	Remote	-		
01-701-1387 / 87/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ HYPERHIDROSIS/ HYPERHIDROSIS	- (-) / Ongoing (.)	Mild	1	Remote	-		
01-701-1392 / 78/W/M	INFECTIONS AND INFESTATIONS/ UPPER RESPIRATORY TRACT INFECTION/ UPPER RESPIRATORY TRACT INFECTION	- (-) / Ongoing (.)	Mild	3	Remote	-		

Copyright © DH

Adverse Events
Safety Analysis Set

Placebo								
Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b		
01-701-1392 / 78/W/M	INFECTIONS AND INFESTATIONS/ UPPER RESPIRATORY TRACT INFECTION/ UPPER RESPIRATORY TRACT INFECTION	- (-) / Ongoing (.)	Mild	1	Remote	-		
01-701-1415 / 85/W/M	GASTROINTESTINAL DISORDERS/ DIARRHOEA/ DIARRHOEA	- (-) / Ongoing (.)	Mild	1	None	-		
01-701-1415 / 85/W/M	INFECTIONS AND INFESTATIONS/ UPPER RESPIRATORY TRACT INFECTION/ UPPER RESPIRATORY TRACT INFECTION	- (-) / Ongoing (.)	Mild	3	None	-		
01-701-1415 / 85/W/M	INFECTIONS AND INFESTATIONS/ UPPER RESPIRATORY TRACT INFECTION/ UPPER RESPIRATORY TRACT INFECTION	- (-) / Ongoing (.)	Mild	1	None	-		
01-701-1415 / 85/W/M	INFECTIONS AND INFESTATIONS/ UPPER RESPIRATORY TRACT INFECTION/ UPPER RESPIRATORY TRACT INFECTION	- (-) / Ongoing (.)	Mild	3	Remote	-		
01-701-1415 / 85/W/M	INFECTIONS AND INFESTATIONS/ UPPER RESPIRATORY TRACT INFECTION/ UPPER RESPIRATORY TRACT INFECTION	- (-) / Ongoing (.)	Mild	1	Remote	-		
01-701-1415 / 85/W/M	RENAL AND URINARY DISORDERS/ MICTURITION URGENCY/ MICTURITION URGENCY	- (-) / Ongoing (.)	Mild	3	None	-		

Copyright © DH

Adverse Events
Safety Analysis Set

Placebo								
Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b		
01-703-1042 / 64/W/M	GASTROINTESTINAL DISORDERS/ DIARRHOEA/ DIARRHOEA	- (-) / Ongoing (.)	Mild	1	Possible	-		
01-703-1042 / 64/W/M	PSYCHIATRIC DISORDERS/ INSOMNIA/ INSOMNIA	- (-) / Ongoing (.)	Mild	1	Remote	-		
01-703-1100 / 84/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE IRRITATION/ APPLICATION SITE IRRITATION	- (-) / Ongoing (.)	Moderate	3	Probable	-		
01-703-1100 / 84/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE IRRITATION/ APPLICATION SITE IRRITATION	- (-) / Ongoing (.)	Mild	3	Probable	-		
01-703-1100 / 84/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE IRRITATION/ APPLICATION SITE IRRITATION	- (-) / Ongoing (.)	Mild	1	Probable	-		
01-703-1100 / 84/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ OEDEMA PERIPHERAL/ OEDEMA PERIPHERAL	- (-) / Ongoing (.)	Moderate	3	Remote	-		
01-703-1100 / 84/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ OEDEMA PERIPHERAL/ OEDEMA PERIPHERAL	- (-) / Ongoing (.)	Mild	3	Remote	-		
01-703-1100 / 84/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ OEDEMA PERIPHERAL/ OEDEMA PERIPHERAL	- (-) / Ongoing (.)	Moderate	1	Remote	-		

Copyright © DH

Adverse Events
Safety Analysis Set

Placebo							
Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b	
01-703-1100 / 84/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ OEDEMA PERIPHERAL/ OEDEMA PERIPHERAL	- (-) / Ongoing (.)	Mild	1	Remote	-	
01-703-1100 / 84/W/F	INFECTIONS AND INFESTATIONS/ UPPER RESPIRATORY TRACT INFECTION/ UPPER RESPIRATORY TRACT INFECTION	- (-) / Ongoing (.)	Moderate	1	Remote	-	
01-703-1100 / 84/W/F	SURGICAL AND MEDICAL PROCEDURES/ CATARACT OPERATION/ CATARACT OPERATION	- (-) / Ongoing (.)	Moderate	1	None	-	
01-703-1175 / 75/W/M	CARDIAC DISORDERS/ ATRIOVENTRICULAR BLOCK SECOND DEGREE/ ATRIOVENTRICULAR BLOCK SECOND DEGREE	- (-) / Ongoing (.)	Severe	3	None	-	
01-703-1210 / 72/W/F	METABOLISM AND NUTRITION DISORDERS/ DECREASED APPETITE/ DECREASED APPETITE	- (-) / Ongoing (.)	Mild	3	Possible	-	
01-703-1210 / 72/W/F	METABOLISM AND NUTRITION DISORDERS/ DECREASED APPETITE/ DECREASED APPETITE	- (-) / Ongoing (.)	Moderate	3	Possible	-	
01-703-1210 / 72/W/F	PSYCHIATRIC DISORDERS/ DISORIENTATION/ DISORIENTATION	- (-) / Ongoing (.)	Mild	3	Remote	-	

Copyright © DH

**Adverse Events
Safety Analysis Set**

Placebo								
Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b		
01-703-1299 / 81/W/F	CARDIAC DISORDERS/ MYOCARDIAL INFARCTION/ MYOCARDIAL INFARCTION	- (-) / Ongoing (.)	Moderate	3	Remote	-		
01-703-1299 / 81/W/F	CARDIAC DISORDERS/ TACHYCARDIA/ TACHYCARDIA	- (-) / Ongoing (.)	Mild	3	Remote	-		
01-703-1299 / 81/W/F	CARDIAC DISORDERS/ TACHYCARDIA/ TACHYCARDIA	- (-) / Ongoing (.)	Moderate	3	Remote	-		
01-703-1299 / 81/W/F	INFECTIONS AND INFESTATIONS/ UPPER RESPIRATORY TRACT INFECTION/ UPPER RESPIRATORY TRACT INFECTION	- (-) / Ongoing (.)	Mild	3	None	-		
01-703-1299 / 81/W/F	INFECTIONS AND INFESTATIONS/ UPPER RESPIRATORY TRACT INFECTION/ UPPER RESPIRATORY TRACT INFECTION	- (-) / Ongoing (.)	Mild	1	None	-		
01-703-1299 / 81/W/F	EYE DISORDERS/ GLAUCOMA/ GLAUCOMA	- (-) / Ongoing (.)	Moderate	3	None	-		
01-703-1299 / 81/W/F	VASCULAR DISORDERS/ HYPOTENSION/ HYPOTENSION	- (-) / Ongoing (.)	Mild	3	Remote	-		
01-703-1299 / 81/W/F	VASCULAR DISORDERS/ HYPOTENSION/ HYPOTENSION	- (-) / Ongoing (.)	Moderate	3	Remote	-		
01-704-1010 / 80/W/M	GASTROINTESTINAL DISORDERS/ DIARRHOEA/ DIARRHOEA	- (-) / Ongoing (.)	Mild	1	None	-		

Copyright © DH

Adverse Events
Safety Analysis Set

Placebo								
Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b		
01-704-1010 / 80/W/M	GASTROINTESTINAL DISORDERS/ VOMITING/ VOMITING	- (-) / Ongoing (.)	Mild	1	None	-		
01-704-1010 / 80/W/M	INFECTIONS AND INFESTATIONS/ CYSTITIS/ CYSTITIS	- (-) / Ongoing (.)	Mild	1	None	-		
01-704-1010 / 80/W/M	MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS/ ARTHRALGIA/ ARTHRALGIA	- (-) / Ongoing (.)	Mild	3	None	-		
01-704-1010 / 80/W/M	INJURY, POISONING AND PROCEDURAL COMPLICATIONS/ CONTUSION/ CONTUSION	- (-) / Ongoing (.)	Mild	3	None	-		
01-704-1010 / 80/W/M	INJURY, POISONING AND PROCEDURAL COMPLICATIONS/ EXCORIATION/ EXCORIATION	- (-) / Ongoing (.)	Mild	3	None	-		
01-704-1010 / 80/W/M	INJURY, POISONING AND PROCEDURAL COMPLICATIONS/ SKIN LACERATION/ SKIN LACERATION	- (-) / Ongoing (.)	Mild	3	None	-		
01-704-1164 / 67/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ OEDEMA PERIPHERAL/ OEDEMA PERIPHERAL	- (-) / Ongoing (.)	Mild	1	None	-		

Copyright © DH

Adverse Events
Safety Analysis Set

Placebo

Subject ID/ Age/Race/Se x	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-704-1164 / 67/W/F	INFECTIONS AND INFESTATIONS/ INFLUENZA/ INFLUENZA	- (-) / Ongoing (.)	Mild	3	None	-
01-704-1164 / 67/W/F	INFECTIONS AND INFESTATIONS/ INFLUENZA/ INFLUENZA	- (-) / Ongoing (.)	Mild	1	None	-
01-704-1351 / 70/W/M	GASTROINTESTINAL DISORDERS/ FLATULENCE/ FLATULENCE	- (-) / Ongoing (.)	Mild	3	None	-
01-704-1351 / 70/W/M	GASTROINTESTINAL DISORDERS/ FLATULENCE/ FLATULENCE	- (-) / Ongoing (.)	Mild	1	None	-
01-704-1351 / 70/W/M	RENAL AND URINARY DISORDERS/ POLLAKIURIA/ POLLAKIURIA	- (-) / Ongoing (.)	Mild	3	None	-
01-704-1351 / 70/W/M	RENAL AND URINARY DISORDERS/ POLLAKIURIA/ POLLAKIURIA	- (-) / Ongoing (.)	Mild	1	None	-
01-704-1388 / 81/W/M	NERVOUS SYSTEM DISORDERS/ HEADACHE/ HEADACHE	- (-) / Ongoing (.)	Moderate	3	None	-
01-704-1435 / 74/W/M	NERVOUS SYSTEM DISORDERS/ PARKINSON'S DISEASE/ PARKINSON'S DISEASE	- (-) / Ongoing (.)	Mild	3	None	-
01-704-1445 / 75/W/M	PSYCHIATRIC DISORDERS/ COMPLETED SUICIDE/ COMPLETED SUICIDE	- (-) / Ongoing (.)	Severe	5	None	-

Copyright © DH

Adverse Events
Safety Analysis Set

Placebo								
Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b		
01-705-1059 / 66/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Moderate	3	Probable	-		
01-705-1186 / 84/W/F	HEPATOBIILIARY DISORDERS/ HYPERBILIRUBINAEMIA/ HYPERBILIRUBINAEMIA	- (-) / Ongoing (.)	Moderate	3	Remote	-		
01-705-1349 / 86/W/F	GASTROINTESTINAL DISORDERS/ NAUSEA/ NAUSEA	- (-) / Ongoing (.)	Mild	1	Remote	-		
01-705-1349 / 86/W/F	GASTROINTESTINAL DISORDERS/ VOMITING/ VOMITING	- (-) / Ongoing (.)	Mild	1	Remote	-		
01-705-1349 / 86/W/F	CARDIAC DISORDERS/ VENTRICULAR HYPERTROPHY/ VENTRICULAR HYPERTROPHY	- (-) / Ongoing (.)	Mild	3	Remote	-		
01-705-1349 / 86/W/F	INVESTIGATIONS/ ELECTROCARDIOGRAM ST SEGMENT DEPRESSION/ ELECTROCARDIOGRAM ST SEGMENT DEPRESSION	- (-) / Ongoing (.)	Mild	3	Remote	-		
01-706-1041 / 64/B/F	GASTROINTESTINAL DISORDERS/ DIARRHOEA/ DIARRHOEA	- (-) / Ongoing (.)	Mild	1	Remote	-		
01-706-1041 / 64/B/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Mild	3	Possible	-		

Copyright © DH

Adverse Events
Safety Analysis Set

Placebo								
Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b		
01-706-1041 / 64/B/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Mild	1	Possible	-		
01-706-1041 / 64/B/F	PSYCHIATRIC DISORDERS/ ANXIETY/ ANXIETY	- (-) / Ongoing (.)	Moderate	3	Remote	-		
01-706-1041 / 64/B/F	PSYCHIATRIC DISORDERS/ ANXIETY/ ANXIETY	- (-) / Ongoing (.)	Mild	3	Remote	-		
01-706-1041 / 64/B/F	PSYCHIATRIC DISORDERS/ IRRITABILITY/ IRRITABILITY	- (-) / Ongoing (.)	Moderate	3	Possible	-		
01-706-1041 / 64/B/F	PSYCHIATRIC DISORDERS/ IRRITABILITY/ IRRITABILITY	- (-) / Ongoing (.)	Moderate	1	Possible	-		
01-706-1041 / 64/B/F	INJURY, POISONING AND PROCEDURAL COMPLICATIONS/ EXCORIATION/ EXCORIATION	- (-) / Ongoing (.)	Mild	3	None	-		
01-706-1041 / 64/B/F	INJURY, POISONING AND PROCEDURAL COMPLICATIONS/ EXCORIATION/ EXCORIATION	- (-) / Ongoing (.)	Mild	1	None	-		
01-707-1206 / 65/W/M	CARDIAC DISORDERS/ SINUS ARRHYTHMIA/ SINUS ARRHYTHMIA	- (-) / Ongoing (.)	Mild	3	Possible	-		
01-707-1206 / 65/W/M	CARDIAC DISORDERS/ SINUS ARRHYTHMIA/ SINUS ARRHYTHMIA	- (-) / Ongoing (.)	Mild	1	Possible	-		

Copyright © DH

Adverse Events
Safety Analysis Set

Placebo								
Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day)/ Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b		
01-707-1206 / 65/W/M	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS/ POSTNASAL DRIP/ POSTNASAL DRIP	- (-)/ Ongoing (.)	Mild	3	None	-		
01-707-1206 / 65/W/M	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS/ POSTNASAL DRIP/ POSTNASAL DRIP	- (-)/ Ongoing (.)	Mild	1	None	-		
01-707-1206 / 65/W/M	EYE DISORDERS/ CONJUNCTIVITIS/ CONJUNCTIVITIS	- (-)/ Ongoing (.)	Moderate	3	Remote	-		
01-707-1206 / 65/W/M	EYE DISORDERS/ CONJUNCTIVITIS/ CONJUNCTIVITIS	- (-)/ Ongoing (.)	Moderate	1	Remote	-		
01-707-1206 / 65/W/M	INVESTIGATIONS/ BLOOD CREATINE PHOSPHOKINASE INCREASED/ BLOOD CREATINE PHOSPHOKINASE INCREASED	- (-)/ Ongoing (.)	Moderate	3	Possible	-		
01-707-1206 / 65/W/M	INVESTIGATIONS/ BLOOD CREATINE PHOSPHOKINASE INCREASED/ BLOOD CREATINE PHOSPHOKINASE INCREASED	- (-)/ Ongoing (.)	Moderate	1	Possible	-		
01-708-1087 / 74/W/F	NERVOUS SYSTEM DISORDERS/ HEADACHE/ HEADACHE	- (-)/ Ongoing (.)	Mild	3	None	-		
01-708-1087 / 74/W/F	NERVOUS SYSTEM DISORDERS/ DIZZINESS/ DIZZINESS	- (-)/ Ongoing (.)	Mild	1	Possible	-		

Copyright © DH

Adverse Events
Safety Analysis Set

Placebo								
Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b		
01-708-1087 / 74/W/F	INVESTIGATIONS/ HEART RATE IRREGULAR/ HEART RATE IRREGULAR	- (-) / Ongoing (.)	Mild	3	Possible	-		
01-708-1087 / 74/W/F	INVESTIGATIONS/ HEART RATE IRREGULAR/ HEART RATE IRREGULAR	- (-) / Ongoing (.)	Mild	1	Possible	-		
01-708-1087 / 74/W/F	INVESTIGATIONS/ HEART RATE IRREGULAR/ HEART RATE IRREGULAR	- (-) / Ongoing (.)	Mild	3	Possible	-		
01-708-1087 / 74/W/F	INVESTIGATIONS/ HEART RATE IRREGULAR/ HEART RATE IRREGULAR	- (-) / Ongoing (.)	Mild	1	Possible	-		
01-708-1158 / 81/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Mild	1	Probable	-		
01-708-1158 / 81/W/F	PSYCHIATRIC DISORDERS/ AGITATION/ AGITATION	- (-) / Ongoing (.)	Mild	3	Remote	-		
01-708-1253 / 61/W/M	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS/ COUGH/ COUGH	- (-) / Ongoing (.)	Mild	3	None	-		
01-708-1253 / 61/W/M	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS/ COUGH/ COUGH	- (-) / Ongoing (.)	Mild	1	None	-		
01-708-1253 / 61/W/M	EYE DISORDERS/ CONJUNCTIVITIS/ CONJUNCTIVITIS	- (-) / Ongoing (.)	Mild	3	None	-		

Copyright © DH

**Adverse Events
Safety Analysis Set**

Placebo								
Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b		
01-708-1253 / 61/W/M	EYE DISORDERS/ CONJUNCTIVITIS/ CONJUNCTIVITIS	- (-) / Ongoing (.)	Mild	1	None	-		
01-708-1253 / 61/W/M	NERVOUS SYSTEM DISORDERS/ DIZZINESS/ DIZZINESS	- (-) / Ongoing (.)	Mild	3	Possible	-		
01-708-1253 / 61/W/M	NERVOUS SYSTEM DISORDERS/ DIZZINESS/ DIZZINESS	- (-) / Ongoing (.)	Mild	1	Possible	-		
01-708-1253 / 61/W/M	INVESTIGATIONS/ HEART RATE INCREASED/ HEART RATE INCREASED	- (-) / Ongoing (.)	Mild	3	Possible	-		
01-708-1253 / 61/W/M	INVESTIGATIONS/ HEART RATE INCREASED/ HEART RATE INCREASED	- (-) / Ongoing (.)	Mild	1	Possible	-		
01-708-1286 / 80/B/F	GASTROINTESTINAL DISORDERS/ ABDOMINAL PAIN/ ABDOMINAL PAIN	- (-) / Ongoing (.)	Mild	1	Remote	-		
01-708-1286 / 80/B/F	GASTROINTESTINAL DISORDERS/ CONSTIPATION/ CONSTIPATION	- (-) / Ongoing (.)	Mild	1	Remote	-		
01-708-1286 / 80/B/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-		
01-708-1286 / 80/B/F	CARDIAC DISORDERS/ MYOCARDIAL INFARCTION/ MYOCARDIAL INFARCTION	- (-) / Ongoing (.)	Mild	3	Remote	-		

Copyright © DH

Adverse Events
Safety Analysis Set

Placebo								
Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b		
01-708-1296 / 57/B/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-		
01-708-1296 / 57/B/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Mild	1	Probable	-		
01-708-1296 / 57/B/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE VESICLES/ APPLICATION SITE VESICLES	- (-) / Ongoing (.)	Mild	3	Probable	-		
01-708-1296 / 57/B/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE VESICLES/ APPLICATION SITE VESICLES	- (-) / Ongoing (.)	Mild	1	Probable	-		
01-708-1296 / 57/B/M	CARDIAC DISORDERS/ ATRIAL HYPERTROPHY/ ATRIAL HYPERTROPHY	- (-) / Ongoing (.)	Mild	3	Remote	-		
01-708-1296 / 57/B/M	CARDIAC DISORDERS/ ATRIAL HYPERTROPHY/ ATRIAL HYPERTROPHY	- (-) / Ongoing (.)	Mild	1	Remote	-		
01-708-1296 / 57/B/M	MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS/ PAIN IN EXTREMITY/ PAIN IN EXTREMITY	- (-) / Ongoing (.)	Mild	1	Remote	-		
01-708-1316 / 74/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE ERYTHEMA/ APPLICATION SITE ERYTHEMA	- (-) / Ongoing (.)	Mild	3	Probable	-		

Copyright © DH

Adverse Events
Safety Analysis Set

Placebo								
Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b		
01-708-1316 / 74/W/F	NERVOUS SYSTEM DISORDERS/ HEADACHE/ HEADACHE	- (-) / Ongoing (.)	Mild	3	Possible	-		
01-709-1088 / 69/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE DERMATITIS/ APPLICATION SITE DERMATITIS	- (-) / Ongoing (.)	Mild	3	Probable	-		
01-709-1088 / 69/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH/ RASH	- (-) / Ongoing (.)	Mild	3	None	-		
01-709-1259 / 82/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ PYREXIA/ PYREXIA	- (-) / Ongoing (.)	Mild	1	None	-		
01-709-1259 / 82/W/M	INFECTIONS AND INFESTATIONS/ LOCALISED INFECTION/ LOCALISED INFECTION	- (-) / Ongoing (.)	Mild	3	None	-		
01-709-1259 / 82/W/M	INFECTIONS AND INFESTATIONS/ LOCALISED INFECTION/ LOCALISED INFECTION	- (-) / Ongoing (.)	Mild	1	None	-		
01-709-1259 / 82/W/M	METABOLISM AND NUTRITION DISORDERS/ DEHYDRATION/ DEHYDRATION	- (-) / Ongoing (.)	Mild	1	None	-		
01-709-1259 / 82/W/M	VASCULAR DISORDERS/ HYPOTENSION/ HYPOTENSION	- (-) / Ongoing (.)	Mild	1	Possible	-		

Copyright © DH

Adverse Events
Safety Analysis Set

Placebo								
Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b		
01-709-1259 / 82/W/M	VASCULAR DISORDERS/ ORTHOSTATIC HYPOTENSION/ ORTHOSTATIC HYPOTENSION	- (-) / Ongoing (.)	Mild	3	Possible	-		
01-709-1259 / 82/W/M	VASCULAR DISORDERS/ ORTHOSTATIC HYPOTENSION/ ORTHOSTATIC HYPOTENSION	- (-) / Ongoing (.)	Mild	1	Possible	-		
01-709-1259 / 82/W/M	INVESTIGATIONS/ BLOOD URINE PRESENT/ BLOOD URINE PRESENT	- (-) / Ongoing (.)	Mild	3	None	-		
01-709-1259 / 82/W/M	INVESTIGATIONS/ CYSTOSCOPY/ CYSTOSCOPY	- (-) / Ongoing (.)	Mild	1	None	-		
01-709-1259 / 82/W/M	REPRODUCTIVE SYSTEM AND BREAST DISORDERS/ BENIGN PROSTATIC HYPERPLASIA/ BENIGN PROSTATIC HYPERPLASIA	- (-) / Ongoing (.)	Mild	3	None	-		
01-709-1259 / 82/W/M	REPRODUCTIVE SYSTEM AND BREAST DISORDERS/ BENIGN PROSTATIC HYPERPLASIA/ BENIGN PROSTATIC HYPERPLASIA	- (-) / Ongoing (.)	Severe	1	None	-		
01-709-1301 / 62/W/F	METABOLISM AND NUTRITION DISORDERS/ DIABETES MELLITUS/ DIABETES MELLITUS	- (-) / Ongoing (.)	Mild	3	None	-		
01-709-1306 / 60/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-		

Copyright © DH

Adverse Events
Safety Analysis Set

Placebo								
Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b		
01-709-1306 / 60/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Moderate	3	Probable	-		
01-709-1306 / 60/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Moderate	1	Probable	-		
01-709-1306 / 60/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE IRRITATION/ APPLICATION SITE IRRITATION	- (-) / Ongoing (.)	Moderate	3	Probable	-		
01-709-1306 / 60/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE IRRITATION/ APPLICATION SITE IRRITATION	- (-) / Ongoing (.)	Moderate	1	Probable	-		
01-709-1306 / 60/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH/ RASH	- (-) / Ongoing (.)	Mild	3	Probable	-		
01-709-1306 / 60/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH/ RASH	- (-) / Ongoing (.)	Moderate	3	Probable	-		
01-709-1306 / 60/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH/ RASH	- (-) / Ongoing (.)	Moderate	1	Probable	-		
01-709-1306 / 60/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ DRUG ERUPTION/ DRUG ERUPTION	- (-) / Ongoing (.)	Mild	1	None	-		

Copyright © DH

Adverse Events
Safety Analysis Set

Placebo							
Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b	
01-709-1312 / 68/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE DERMATITIS/ APPLICATION SITE DERMATITIS	- (-) / Ongoing (.)	Mild	3	Probable	-	
01-709-1312 / 68/W/F	INVESTIGATIONS/ ELECTROCARDIOGRAM ST SEGMENT DEPRESSION/ ELECTROCARDIOGRAM ST SEGMENT DEPRESSION	- (-) / Ongoing (.)	Mild	3	Remote	-	
01-709-1339 / 81/W/M	NERVOUS SYSTEM DISORDERS/ HEADACHE/ HEADACHE	- (-) / Ongoing (.)	Moderate	3	None	-	
01-709-1339 / 81/W/M	INVESTIGATIONS/ BLOOD ALKALINE PHOSPHATASE INCREASED/ BLOOD ALKALINE PHOSPHATASE INCREASED	- (-) / Ongoing (.)	Moderate	3	None	-	
01-710-1027 / 83/W/M	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS/ HAEMOPTYSIS/ HAEMOPTYSIS	- (-) / Ongoing (.)	Mild	3	None	-	
01-710-1027 / 83/W/M	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS/ HAEMOPTYSIS/ HAEMOPTYSIS	- (-) / Ongoing (.)	Mild	1	None	-	
01-710-1027 / 83/W/M	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS/ RALES/ RALES	- (-) / Ongoing (.)	Mild	3	None	-	

Copyright © DH

Adverse Events
Safety Analysis Set

Placebo								
Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b		
01-710-1027 / 83/W/M	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS/ RALES/ RALES	- (-) / Ongoing (.)	Mild	1	None	-		
01-710-1060 / 82/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Mild	1	Possible	-		
01-710-1060 / 82/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Mild	1	Possible	-		
01-710-1060 / 82/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE INDURATION/ APPLICATION SITE INDURATION	- (-) / Ongoing (.)	Mild	1	Possible	-		
01-710-1060 / 82/W/M	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS/ NASAL CONGESTION/ NASAL CONGESTION	- (-) / Ongoing (.)	Mild	1	None	-		
01-710-1060 / 82/W/M	PSYCHIATRIC DISORDERS/ INSOMNIA/ INSOMNIA	- (-) / Ongoing (.)	Mild	3	None	-		
01-710-1060 / 82/W/M	PSYCHIATRIC DISORDERS/ INSOMNIA/ INSOMNIA	- (-) / Ongoing (.)	Mild	1	None	-		
01-710-1060 / 82/W/M	INJURY, POISONING AND PROCEDURAL COMPLICATIONS/ FALL/ FALL	- (-) / Ongoing (.)	Mild	1	None	-		

Copyright © DH

**Adverse Events
Safety Analysis Set**

Placebo								
Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b		
01-710-1060 / 82/W/M	INJURY, POISONING AND PROCEDURAL COMPLICATIONS/ FALL/ FALL	- (-) / Ongoing (.)	Mild	1	None	-		
01-710-1077 / 76/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE DERMATITIS/ APPLICATION SITE DERMATITIS	- (-) / Ongoing (.)	Mild	1	Possible	-		
01-710-1077 / 76/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ SKIN IRRITATION/ SKIN IRRITATION	- (-) / Ongoing (.)	Mild	3	Possible	-		
01-710-1077 / 76/W/F	MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS/ ARTHRITIS/ ARTHRITIS	- (-) / Ongoing (.)	Severe	3	None	-		
01-710-1077 / 76/W/F	MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS/ ARTHRITIS/ ARTHRITIS	- (-) / Ongoing (.)	Moderate	3	None	-		
01-710-1077 / 76/W/F	PSYCHIATRIC DISORDERS/ AGITATION/ AGITATION	- (-) / Ongoing (.)	Mild	3	Remote	-		
01-710-1083 / 89/W/F	CARDIAC DISORDERS/ MYOCARDIAL INFARCTION/ MYOCARDIAL INFARCTION	- (-) / Ongoing (.)	Severe	5	Possible	-		

Copyright © DH

Adverse Events
Safety Analysis Set

Placebo								
Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b		
01-710-1183 / 80/W/F	CARDIAC DISORDERS/ ATRIOVENTRICULAR BLOCK FIRST DEGREE/ ATRIOVENTRICULAR BLOCK FIRST DEGREE	- (-) / Ongoing (.)	Mild	3	Possible	-		
01-710-1183 / 80/W/F	CARDIAC DISORDERS/ SINUS BRADYCARDIA/ SINUS BRADYCARDIA	- (-) / Ongoing (.)	Moderate	3	Possible	-		
01-710-1264 / 78/W/M	GASTROINTESTINAL DISORDERS/ DIARRHOEA/ DIARRHOEA	- (-) / Ongoing (.)	Mild	1	Possible	-		
01-710-1264 / 78/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ CHILLS/ CHILLS	- (-) / Ongoing (.)	Moderate	1	Possible	-		
01-710-1264 / 78/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ CHILLS/ CHILLS	- (-) / Ongoing (.)	Moderate	1	Possible	-		
01-710-1264 / 78/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ CHILLS/ CHILLS	- (-) / Ongoing (.)	Moderate	1	Possible	-		
01-710-1264 / 78/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Mild	3	Possible	-		
01-710-1264 / 78/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH/ RASH	- (-) / Ongoing (.)	Mild	3	Possible	-		

Copyright © DH

Adverse Events
Safety Analysis Set

Placebo								
Subject ID/ Age/Race/Se x	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b		
01-710-1264 / 78/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ COLD SWEAT/ COLD SWEAT	- (-) / Ongoing (.)	Moderate	1	Possible	-		
01-710-1264 / 78/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ COLD SWEAT/ COLD SWEAT	- (-) / Ongoing (.)	Moderate	1	Possible	-		
01-710-1264 / 78/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ COLD SWEAT/ COLD SWEAT	- (-) / Ongoing (.)	Moderate	1	Possible	-		
01-710-1271 / 86/W/F	CARDIAC DISORDERS/ MYOCARDIAL INFARCTION/ MYOCARDIAL INFARCTION	- (-) / Ongoing (.)	Severe	1	Possible	-		
01-710-1271 / 86/W/F	CARDIAC DISORDERS/ ATRIAL FIBRILLATION/ ATRIAL FIBRILLATION	- (-) / Ongoing (.)	Moderate	1	Possible	-		
01-710-1271 / 86/W/F	CARDIAC DISORDERS/ CARDIAC FAILURE CONGESTIVE/ CARDIAC FAILURE CONGESTIVE	- (-) / Ongoing (.)	Moderate	3	Possible	-		
01-710-1271 / 86/W/F	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS/ DYSPNOEA/ DYSPNOEA	- (-) / Ongoing (.)	Moderate	1	Possible	-		
01-710-1271 / 86/W/F	METABOLISM AND NUTRITION DISORDERS/ HYPONATRAEMIA/ HYPONATRAEMIA	- (-) / Ongoing (.)	Moderate	1	Remote	-		

Copyright © DH

**Adverse Events
Safety Analysis Set**

Placebo								
Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b		
01-710-1314 / 78/W/F	INFECTIONS AND INFESTATIONS/ NASOPHARYNGITIS/ NASOPHARYNGITIS	- (-) / Ongoing (.)	Mild	3	None	-		
01-710-1314 / 78/W/F	INFECTIONS AND INFESTATIONS/ NASOPHARYNGITIS/ NASOPHARYNGITIS	- (-) / Ongoing (.)	Mild	1	None	-		
01-710-1315 / 83/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Moderate	3	Possible	-		
01-710-1315 / 83/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Moderate	1	Possible	-		
01-710-1315 / 83/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Mild	3	Possible	-		
01-710-1315 / 83/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Mild	1	Possible	-		
01-710-1315 / 83/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH/ RASH	- (-) / Ongoing (.)	Moderate	3	Possible	-		
01-710-1315 / 83/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH/ RASH	- (-) / Ongoing (.)	Moderate	1	Possible	-		

Copyright © DH

Adverse Events
Safety Analysis Set

Placebo								
Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b		
01-710-1315 / 83/W/F	NERVOUS SYSTEM DISORDERS/ HEADACHE/ HEADACHE	- (-) / Ongoing (.)	Mild	1	Remote	-		
01-710-1368 / 88/W/F	NERVOUS SYSTEM DISORDERS/ PSYCHOMOTOR HYPERACTIVITY/ PSYCHOMOTOR HYPERACTIVITY	- (-) / Ongoing (.)	Mild	3	Remote	-		
01-710-1368 / 88/W/F	PSYCHIATRIC DISORDERS/ DELUSION/ DELUSION	- (-) / Ongoing (.)	Mild	3	Remote	-		
01-710-1368 / 88/W/F	INJURY, POISONING AND PROCEDURAL COMPLICATIONS/ HIP FRACTURE/ HIP FRACTURE	- (-) / Ongoing (.)	Severe	3	None	-		
01-710-1368 / 88/W/F	INJURY, POISONING AND PROCEDURAL COMPLICATIONS/ HIP FRACTURE/ HIP FRACTURE	- (-) / Ongoing (.)	Severe	1	None	-		
01-711-1036 / 70/B/M	GASTROINTESTINAL DISORDERS/ GLOSSITIS/ GLOSSITIS	- (-) / Ongoing (.)	Mild	3	None	-		
01-711-1036 / 70/B/M	INFECTIONS AND INFESTATIONS/ EAR INFECTION/ EAR INFECTION	- (-) / Ongoing (.)	Mild	3	None	-		
01-711-1036 / 70/B/M	INFECTIONS AND INFESTATIONS/ EAR INFECTION/ EAR INFECTION	- (-) / Ongoing (.)	Mild	1	None	-		
01-711-1036 / 70/B/M	NERVOUS SYSTEM DISORDERS/ HEADACHE/ HEADACHE	- (-) / Ongoing (.)	Mild	3	None	-		

Copyright © DH

Adverse Events
Safety Analysis Set

Placebo								
Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b		
01-713-1179 / 64/W/F	GASTROINTESTINAL DISORDERS/ DYSPEPSIA/ DYSPEPSIA	- (-) / Ongoing (.)	Mild	1	Possible	-		
01-713-1179 / 64/W/F	GASTROINTESTINAL DISORDERS/ DYSPEPSIA/ DYSPEPSIA	- (-) / Ongoing (.)	Mild	3	Possible	-		
01-713-1179 / 64/W/F	GASTROINTESTINAL DISORDERS/ GASTROESOPHAGEAL REFLUX DISEASE/ GASTROESOPHAGEAL REFLUX DISEASE	- (-) / Ongoing (.)	Mild	3	Possible	-		
01-713-1179 / 64/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ ASTHENIA/ ASTHENIA	- (-) / Ongoing (.)	Moderate	3	Possible	-		
01-713-1179 / 64/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ ASTHENIA/ ASTHENIA	- (-) / Ongoing (.)	Mild	3	Possible	-		
01-713-1179 / 64/W/F	INFECTIONS AND INFESTATIONS/ URINARY TRACT INFECTION/ URINARY TRACT INFECTION	- (-) / Ongoing (.)	Mild	3	Remote	-		
01-713-1179 / 64/W/F	INFECTIONS AND INFESTATIONS/ URINARY TRACT INFECTION/ URINARY TRACT INFECTION	- (-) / Ongoing (.)	Mild	1	Remote	-		
01-713-1179 / 64/W/F	INFECTIONS AND INFESTATIONS/ CERVICITIS/ CERVICITIS	- (-) / Ongoing (.)	Mild	3	Remote	-		
01-713-1179 / 64/W/F	INFECTIONS AND INFESTATIONS/ CERVICITIS/ CERVICITIS	- (-) / Ongoing (.)	Mild	1	Remote	-		

Copyright © DH

Adverse Events
Safety Analysis Set

Placebo								
Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b		
01-713-1179 / 64/W/F	INFECTIONS AND INFESTATIONS/ GASTROENTERITIS VIRAL/ GASTROENTERITIS VIRAL	- (-) / Ongoing (.)	Moderate	1	Remote	-		
01-713-1179 / 64/W/F	INFECTIONS AND INFESTATIONS/ VAGINAL MYCOSIS/ VAGINAL MYCOSIS	- (-) / Ongoing (.)	Mild	3	Remote	-		
01-713-1179 / 64/W/F	INFECTIONS AND INFESTATIONS/ VAGINAL MYCOSIS/ VAGINAL MYCOSIS	- (-) / Ongoing (.)	Mild	1	Remote	-		
01-713-1179 / 64/W/F	RENAL AND URINARY DISORDERS/ DYSURIA/ DYSURIA	- (-) / Ongoing (.)	Mild	1	Remote	-		
01-713-1179 / 64/W/F	REPRODUCTIVE SYSTEM AND BREAST DISORDERS/ PELVIC PAIN/ PELVIC PAIN	- (-) / Ongoing (.)	Mild	3	Possible	-		
01-713-1179 / 64/W/F	REPRODUCTIVE SYSTEM AND BREAST DISORDERS/ PELVIC PAIN/ PELVIC PAIN	- (-) / Ongoing (.)	Mild	1	Possible	-		
01-713-1256 / 71/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE DERMATITIS/ APPLICATION SITE DERMATITIS	- (-) / Ongoing (.)	Mild	3	Probable	-		
01-713-1256 / 71/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE DERMATITIS/ APPLICATION SITE DERMATITIS	- (-) / Ongoing (.)	Mild	1	Probable	-		

Copyright © DH

Adverse Events
Safety Analysis Set

Placebo								
Subject ID/ Age/Race/Se x	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b		
01-713-1269 / 73/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE ERYTHEMA/ APPLICATION SITE ERYTHEMA	- (-) / Ongoing (.)	Mild	3	Probable	-		
01-713-1269 / 73/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH/ RASH	- (-) / Ongoing (.)	Moderate	3	Remote	-		
01-713-1269 / 73/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH/ RASH	- (-) / Ongoing (.)	Mild	3	Remote	-		
01-713-1269 / 73/W/M	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS/ COUGH/ COUGH	- (-) / Ongoing (.)	Mild	3	Remote	-		
01-713-1269 / 73/W/M	MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS/ SHOULDER PAIN/ SHOULDER PAIN	- (-) / Ongoing (.)	Mild	3	Possible	-		
01-713-1269 / 73/W/M	MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS/ SHOULDER PAIN/ SHOULDER PAIN	- (-) / Ongoing (.)	Moderate	3	Possible	-		
01-714-1035 / 88/W/F	CARDIAC DISORDERS/ BUNDLE BRANCH BLOCK RIGHT/ BUNDLE BRANCH BLOCK RIGHT	- (-) / Ongoing (.)	Mild	3	Remote	-		
01-714-1035 / 88/W/F	CARDIAC DISORDERS/ BUNDLE BRANCH BLOCK RIGHT/ BUNDLE BRANCH BLOCK RIGHT	- (-) / Ongoing (.)	Mild	1	Remote	-		

Copyright © DH

**Adverse Events
Safety Analysis Set**

Placebo								
Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b		
01-714-1035 / 88/W/F	CARDIAC DISORDERS/ SUPRAVENTRICULAR EXTRASYSTOLES/ SUPRAVENTRICULAR EXTRASYSTOLES	- (-) / Ongoing (.)	Mild	3	Remote	-		
01-714-1035 / 88/W/F	CARDIAC DISORDERS/ SUPRAVENTRICULAR EXTRASYSTOLES/ SUPRAVENTRICULAR EXTRASYSTOLES	- (-) / Ongoing (.)	Mild	1	Remote	-		
01-714-1035 / 88/W/F	INFECTIONS AND INFESTATIONS/ BRONCHITIS/ BRONCHITIS	- (-) / Ongoing (.)	Moderate	1	None	-		
01-714-1035 / 88/W/F	INVESTIGATIONS/ ELECTROCARDIOGRAM ST SEGMENT DEPRESSION/ ELECTROCARDIOGRAM ST SEGMENT DEPRESSION	- (-) / Ongoing (.)	Mild	3	Remote	-		
01-714-1035 / 88/W/F	INVESTIGATIONS/ ELECTROCARDIOGRAM T WAVE INVERSION/ ELECTROCARDIOGRAM T WAVE INVERSION	- (-) / Ongoing (.)	Mild	3	Remote	-		
01-714-1375 / 78/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Moderate	3	Probable	-		
01-714-1375 / 78/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Mild	3	Probable	-		

Copyright © DH

Adverse Events
Safety Analysis Set

Placebo								
Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b		
01-714-1375 / 78/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Moderate	3	Probable	-		
01-714-1375 / 78/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-		
01-714-1375 / 78/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ SKIN IRRITATION/ SKIN IRRITATION	- (-) / Ongoing (.)	Moderate	3	None	-		
01-714-1375 / 78/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ SKIN IRRITATION/ SKIN IRRITATION	- (-) / Ongoing (.)	Moderate	1	None	-		
01-714-1375 / 78/W/F	EAR AND LABYRINTH DISORDERS/ EAR PAIN/ EAR PAIN	- (-) / Ongoing (.)	Mild	3	None	-		
01-714-1375 / 78/W/F	EAR AND LABYRINTH DISORDERS/ EAR PAIN/ EAR PAIN	- (-) / Ongoing (.)	Mild	1	None	-		
01-715-1207 / 78/W/F	RENAL AND URINARY DISORDERS/ NEPHROLITHIASIS/ NEPHROLITHIASIS	- (-) / Ongoing (.)	Moderate	1	None	-		
01-716-1024 / 87/W/F	INFECTIONS AND INFESTATIONS/ NASOPHARYNGITIS/ NASOPHARYNGITIS	- (-) / Ongoing (.)	Moderate	3	None	-		
01-716-1024 / 87/W/F	INFECTIONS AND INFESTATIONS/ NASOPHARYNGITIS/ NASOPHARYNGITIS	- (-) / Ongoing (.)	Moderate	1	None	-		

Copyright © DH

Adverse Events
Safety Analysis Set

Placebo								
Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b		
01-716-1024 / 87/W/F	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS/ EMPHYSEMA/ EMPHYSEMA	- (-) / Ongoing (.)	Mild	3	Probable	-		
01-716-1026 / 73/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Mild	3	Possible	-		
01-716-1026 / 73/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ HYPERHIDROSIS/ HYPERHIDROSIS	- (-) / Ongoing (.)	Mild	3	Possible	-		
01-716-1026 / 73/W/F	INFECTIONS AND INFESTATIONS/ EAR INFECTION/ EAR INFECTION	- (-) / Ongoing (.)	Mild	1	None	-		
01-716-1026 / 73/W/F	INFECTIONS AND INFESTATIONS/ EAR INFECTION/ EAR INFECTION	- (-) / Ongoing (.)	Mild	1	None	-		
01-716-1026 / 73/W/F	INVESTIGATIONS/ ELECTROCARDIOGRAM T WAVE INVERSION/ ELECTROCARDIOGRAM T WAVE INVERSION	- (-) / Ongoing (.)	Mild	3	Remote	-		
01-716-1026 / 73/W/F	INVESTIGATIONS/ ELECTROCARDIOGRAM T WAVE INVERSION/ ELECTROCARDIOGRAM T WAVE INVERSION	- (-) / Ongoing (.)	Mild	1	Remote	-		

Copyright © DH

Adverse Events
Safety Analysis Set

Placebo								
Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day)/ Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b		
01-716-1026 / 73/W/F	INVESTIGATIONS/ ELECTROCARDIOGRAM T WAVE AMPLITUDE DECREASED/ ELECTROCARDIOGRAM T WAVE AMPLITUDE DECREASED	- (-)/ Ongoing (.)	Mild	3	Remote	-		
01-716-1044 / 74/W/M	GASTROINTESTINAL DISORDERS/ DIARRHOEA/ DIARRHOEA	- (-)/ Ongoing (.)	Mild	3	Possible	-		
01-716-1044 / 74/W/M	GASTROINTESTINAL DISORDERS/ DIARRHOEA/ DIARRHOEA	- (-)/ Ongoing (.)	Mild	1	Possible	-		
01-716-1044 / 74/W/M	PSYCHIATRIC DISORDERS/ CONFUSIONAL STATE/ CONFUSIONAL STATE	- (-)/ Ongoing (.)	Mild	3	Possible	-		
01-716-1108 / 86/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-)/ Ongoing (.)	Mild	3	Probable	-		
01-716-1108 / 86/W/F	INVESTIGATIONS/ ELECTROCARDIOGRAM ST SEGMENT DEPRESSION/ ELECTROCARDIOGRAM ST SEGMENT DEPRESSION	- (-)/ Ongoing (.)	Mild	3	Possible	-		
01-716-1160 / 83/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-)/ Ongoing (.)	Mild	3	Probable	-		

Copyright © DH

Adverse Events
Safety Analysis Set

Placebo								
Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b		
01-716-1160 / 83/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-		
01-716-1177 / 72/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Mild	3	Probable	-		
01-716-1308 / 76/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Mild	3	Probable	-		
01-716-1441 / 85/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Mild	3	Probable	-		
01-717-1201 / 85/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ SKIN IRRITATION/ SKIN IRRITATION	- (-) / Ongoing (.)	Mild	3	Probable	-		
01-717-1201 / 85/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ALOPECIA/ ALOPECIA	- (-) / Ongoing (.)	Mild	3	Remote	-		
01-717-1344 / 64/W/F	GASTROINTESTINAL DISORDERS/ NAUSEA/ NAUSEA	- (-) / Ongoing (.)	Moderate	1	Remote	-		

Copyright © DH

Adverse Events
Safety Analysis Set

Placebo								
Subject ID/ Age/Race/Se x	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b		
01-717-1344 / 64/W/F	GASTROINTESTINAL DISORDERS/ VOMITING/ VOMITING	- (-) / Ongoing (.)	Moderate	1	Remote	-		
01-717-1344 / 64/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ FATIGUE/ FATIGUE	- (-) / Ongoing (.)	Mild	3	Possible	-		
01-717-1344 / 64/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ FATIGUE/ FATIGUE	- (-) / Ongoing (.)	Mild	1	Possible	-		
01-717-1344 / 64/W/F	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS/ NASAL CONGESTION/ NASAL CONGESTION	- (-) / Ongoing (.)	Mild	1	Remote	-		
01-718-1139 / 77/W/M	GASTROINTESTINAL DISORDERS/ DIARRHOEA/ DIARRHOEA	- (-) / Ongoing (.)	Mild	1	None	-		
01-718-1139 / 77/W/M	NERVOUS SYSTEM DISORDERS/ SOMNOLENCE/ SOMNOLENCE	- (-) / Ongoing (.)	Moderate	3	Possible	-		
01-718-1139 / 77/W/M	NERVOUS SYSTEM DISORDERS/ SOMNOLENCE/ SOMNOLENCE	- (-) / Ongoing (.)	Moderate	1	Possible	-		
01-718-1150 / 73/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE IRRITATION/ APPLICATION SITE IRRITATION	- (-) / Ongoing (.)	Mild	1	Probable	-		

Copyright © DH

Adverse Events
Safety Analysis Set

Placebo								
Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b		
01-718-1150 / 73/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE IRRITATION/ APPLICATION SITE IRRITATION	- (-) / Ongoing (.)	Mild	3	Probable	-		
01-718-1150 / 73/W/F	CARDIAC DISORDERS/ SINUS BRADYCARDIA/ SINUS BRADYCARDIA	- (-) / Ongoing (.)	Mild	3	Possible	-		
01-718-1150 / 73/W/F	CARDIAC DISORDERS/ BRADYCARDIA/ BRADYCARDIA	- (-) / Ongoing (.)	Mild	3	Possible	-		
01-718-1150 / 73/W/F	CARDIAC DISORDERS/ BRADYCARDIA/ BRADYCARDIA	- (-) / Ongoing (.)	Mild	1	Possible	-		
01-718-1150 / 73/W/F	CARDIAC DISORDERS/ BRADYCARDIA/ BRADYCARDIA	- (-) / Ongoing (.)	Mild	3	Possible	-		
01-718-1150 / 73/W/F	CARDIAC DISORDERS/ BRADYCARDIA/ BRADYCARDIA	- (-) / Ongoing (.)	Mild	1	Possible	-		
01-718-1150 / 73/W/F	INFECTIONS AND INFESTATIONS/ UPPER RESPIRATORY TRACT INFECTION/ UPPER RESPIRATORY TRACT INFECTION	- (-) / Ongoing (.)	Moderate	3	None	-		
01-718-1150 / 73/W/F	INFECTIONS AND INFESTATIONS/ UPPER RESPIRATORY TRACT INFECTION/ UPPER RESPIRATORY TRACT INFECTION	- (-) / Ongoing (.)	Moderate	1	None	-		

Copyright © DH

Adverse Events
Safety Analysis Set

Placebo								
Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b		
01-718-1150 / 73/W/F	METABOLISM AND NUTRITION DISORDERS/ FOOD CRAVING/ FOOD CRAVING	- (-) / Ongoing (.)	Mild	3	Possible	-		
01-718-1355 / 79/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE DERMATITIS/ APPLICATION SITE DERMATITIS	- (-) / Ongoing (.)	Mild	1	Probable	-		
01-718-1355 / 79/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE DERMATITIS/ APPLICATION SITE DERMATITIS	- (-) / Ongoing (.)	Mild	1	Probable	-		
01-718-1355 / 79/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE DERMATITIS/ APPLICATION SITE DERMATITIS	- (-) / Ongoing (.)	Mild	1	Probable	-		
01-718-1355 / 79/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE DERMATITIS/ APPLICATION SITE DERMATITIS	- (-) / Ongoing (.)	Mild	1	Probable	-		
01-718-1355 / 79/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE REACTION/ APPLICATION SITE REACTION	- (-) / Ongoing (.)	Mild	3	Probable	-		
01-718-1355 / 79/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE REACTION/ APPLICATION SITE REACTION	- (-) / Ongoing (.)	Moderate	1	Probable	-		

Copyright © DH

Adverse Events
Safety Analysis Set

Placebo								
Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b		
01-718-1355 / 79/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ DERMATITIS ATOPIC/ DERMATITIS ATOPIC	- (-) / Ongoing (.)	Moderate	3	None	-		
01-718-1355 / 79/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ SKIN ULCER/ SKIN ULCER	- (-) / Ongoing (.)	Moderate	3	Probable	-		
01-718-1355 / 79/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ SKIN ULCER/ SKIN ULCER	- (-) / Ongoing (.)	Moderate	1	Probable	-		
01-718-1355 / 79/W/M	NERVOUS SYSTEM DISORDERS/ SOMNOLENCE/ SOMNOLENCE	- (-) / Ongoing (.)	Moderate	3	None	-		
01-718-1355 / 79/W/M	PSYCHIATRIC DISORDERS/ CONFUSIONAL STATE/ CONFUSIONAL STATE	- (-) / Ongoing (.)	Moderate	3	Remote	-		
01-718-1355 / 79/W/M	VASCULAR DISORDERS/ HYPERTENSION/ HYPERTENSION	- (-) / Ongoing (.)	Moderate	3	Remote	-		
01-718-1355 / 79/W/M	VASCULAR DISORDERS/ HYPERTENSION/ HYPERTENSION	- (-) / Ongoing (.)	Moderate	1	Remote	-		

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline Low Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-701-1097 / 68/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Mild	3	Possible	-
01-701-1097 / 68/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Moderate	3	Possible	-
01-701-1097 / 68/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE VESICLES/ APPLICATION SITE VESICLES	- (-) / Ongoing (.)	Mild	1	Probable	-
01-701-1097 / 68/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Mild	3	Possible	-
01-701-1097 / 68/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS GENERALISED/ PRURITUS GENERALISED	- (-) / Ongoing (.)	Moderate	1	Possible	-
01-701-1097 / 68/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS GENERALISED/ PRURITUS GENERALISED	- (-) / Ongoing (.)	Moderate	1	Possible	-
01-701-1097 / 68/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS GENERALISED/ PRURITUS GENERALISED	- (-) / Ongoing (.)	Moderate	1	Possible	-
01-701-1097 / 68/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS GENERALISED/ PRURITUS GENERALISED	- (-) / Ongoing (.)	Moderate	1	Possible	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline Low Dose

Subject ID/ Age/Race/Se x	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-701-1097 / 68/W/M	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS/ NASAL CONGESTION/ NASAL CONGESTION	- (-) / Ongoing (.)	Mild	1	None	-
01-701-1097 / 68/W/M	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS/ PHARYNGOLARYNGEAL PAIN/ PHARYNGOLARYNGEAL PAIN	- (-) / Ongoing (.)	Mild	1	None	-
01-701-1111 / 81/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Mild	3	None	-
01-701-1111 / 81/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Mild	1	None	-
01-701-1111 / 81/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Mild	3	None	-
01-701-1111 / 81/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Mild	1	None	-
01-701-1111 / 81/W/F	INFECTIONS AND INFESTATIONS/ LOCALISED INFECTION/ LOCALISED INFECTION	- (-) / Ongoing (.)	Moderate	3	None	-
01-701-1111 / 81/W/F	INFECTIONS AND INFESTATIONS/ CELLULITIS/ CELLULITIS	- (-) / Ongoing (.)	Moderate	3	None	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline Low Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-701-1111 / 81/W/F	MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS/ ARTHRALGIA/ ARTHRALGIA	- (-) / Ongoing (.)	Moderate	3	None	-
01-701-1111 / 81/W/F	RENAL AND URINARY DISORDERS/ MICTURITION URGENCY/ MICTURITION URGENCY	- (-) / Ongoing (.)	Mild	3	None	-
01-701-1115 / 84/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE ERYTHEMA/ APPLICATION SITE ERYTHEMA	- (-) / Ongoing (.)	Mild	3	Probable	-
01-701-1115 / 84/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE ERYTHEMA/ APPLICATION SITE ERYTHEMA	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-701-1115 / 84/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-
01-701-1115 / 84/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-701-1115 / 84/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE IRRITATION/ APPLICATION SITE IRRITATION	- (-) / Ongoing (.)	Mild	3	Possible	-
01-701-1115 / 84/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE IRRITATION/ APPLICATION SITE IRRITATION	- (-) / Ongoing (.)	Mild	1	Possible	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline Low Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-701-1115 / 84/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE IRRITATION/ APPLICATION SITE IRRITATION	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-701-1115 / 84/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE DERMATITIS/ APPLICATION SITE DERMATITIS	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-701-1115 / 84/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ FATIGUE/ FATIGUE	- (-) / Ongoing (.)	Moderate	3	Remote	-
01-701-1188 / 71/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE URTICARIA/ APPLICATION SITE URTICARIA	- (-) / Ongoing (.)	Mild	3	Probable	-
01-701-1188 / 71/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Mild	3	Probable	-
01-701-1188 / 71/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-701-1188 / 71/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline Low Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-701-1188 / 71/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-701-1188 / 71/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ URTICARIA/ URTICARIA	- (-) / Ongoing (.)	Mild	3	Probable	-
01-701-1188 / 71/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ URTICARIA/ URTICARIA	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-701-1188 / 71/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ URTICARIA/ URTICARIA	- (-) / Ongoing (.)	Mild	3	Probable	-
01-701-1192 / 80/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE ERYTHEMA/ APPLICATION SITE ERYTHEMA	- (-) / Ongoing (.)	Mild	3	Probable	-
01-701-1192 / 80/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-
01-701-1192 / 80/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE IRRITATION/ APPLICATION SITE IRRITATION	- (-) / Ongoing (.)	Mild	3	Probable	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline Low Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-701-1192 / 80/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE IRRITATION/ APPLICATION SITE IRRITATION	- (-) / Ongoing (.)	Mild	1	Probable	-
01-701-1192 / 80/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ SECRETION DISCHARGE/ SECRETION DISCHARGE	- (-) / Ongoing (.)	Mild	3	None	-
01-701-1192 / 80/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ SECRETION DISCHARGE/ SECRETION DISCHARGE	- (-) / Ongoing (.)	Mild	1	None	-
01-701-1192 / 80/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Mild	3	None	-
01-701-1192 / 80/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Mild	1	None	-
01-701-1192 / 80/W/F	INFECTIONS AND INFESTATIONS/ PNEUMONIA/ PNEUMONIA	- (-) / Ongoing (.)	Moderate	3	None	-
01-701-1192 / 80/W/F	INFECTIONS AND INFESTATIONS/ PNEUMONIA/ PNEUMONIA	- (-) / Ongoing (.)	Moderate	1	None	-
01-701-1192 / 80/W/F	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS/ COUGH/ COUGH	- (-) / Ongoing (.)	Moderate	3	None	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline Low Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-701-1192 / 80/W/F	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS/ COUGH/ COUGH	- (-) / Ongoing (.)	Mild	3	None	-
01-701-1192 / 80/W/F	MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS/ MUSCULAR WEAKNESS/ MUSCULAR WEAKNESS	- (-) / Ongoing (.)	Moderate	3	None	-
01-701-1192 / 80/W/F	MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS/ MUSCULAR WEAKNESS/ MUSCULAR WEAKNESS	- (-) / Ongoing (.)	Moderate	1	None	-
01-701-1192 / 80/W/F	INVESTIGATIONS/ NASAL MUCOSA BIOPSY/ NASAL MUCOSA BIOPSY	- (-) / Ongoing (.)	Mild	1	None	-
01-701-1211 / 76/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE ERYTHEMA/ APPLICATION SITE ERYTHEMA	- (-) / Ongoing (.)	Mild	3	Possible	-
01-701-1211 / 76/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Mild	3	Possible	-
01-701-1211 / 76/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ SUDDEN DEATH/ SUDDEN DEATH	- (-) / Ongoing (.)	Severe	5	None	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline Low Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-701-1211 / 76/W/F	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS/ DYSпноEA/ DYSпноEA	- (-) / Ongoing (.)	Moderate	3	None	-
01-701-1211 / 76/W/F	MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS/ SHOULDER PAIN/ SHOULDER PAIN	- (-) / Ongoing (.)	Mild	3	None	-
01-701-1211 / 76/W/F	RENAL AND URINARY DISORDERS/ INCONTINENCE/ INCONTINENCE	- (-) / Ongoing (.)	Mild	3	None	-
01-701-1211 / 76/W/F	PSYCHIATRIC DISORDERS/ CONFUSIONAL STATE/ CONFUSIONAL STATE	- (-) / Ongoing (.)	Moderate	3	None	-
01-701-1211 / 76/W/F	INJURY, POISONING AND PROCEDURAL COMPLICATIONS/ SKIN LACERATION/ SKIN LACERATION	- (-) / Ongoing (.)	Mild	3	None	-
01-701-1211 / 76/W/F	INJURY, POISONING AND PROCEDURAL COMPLICATIONS/ JOINT DISLOCATION/ JOINT DISLOCATION	- (-) / Ongoing (.)	Moderate	1	None	-
01-701-1294 / 67/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE ERYTHEMA/ APPLICATION SITE ERYTHEMA	- (-) / Ongoing (.)	Mild	3	Probable	-
01-701-1294 / 67/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE ERYTHEMA/ APPLICATION SITE ERYTHEMA	- (-) / Ongoing (.)	Moderate	3	Probable	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline Low Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-701-1294 / 67/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Moderate	1	None	-
01-701-1294 / 67/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Mild	3	Possible	-
01-701-1294 / 67/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Moderate	3	Possible	-
01-701-1294 / 67/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH ERYTHEMATOUS/ RASH ERYTHEMATOUS	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-701-1317 / 68/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE ERYTHEMA/ APPLICATION SITE ERYTHEMA	- (-) / Ongoing (.)	Mild	3	Possible	-
01-701-1317 / 68/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Mild	3	Possible	-
01-701-1317 / 68/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ FATIGUE/ FATIGUE	- (-) / Ongoing (.)	Mild	3	Remote	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline Low Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-701-1317 / 68/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE URTICARIA/ APPLICATION SITE URTICARIA	- (-) / Ongoing (.)	Mild	3	Possible	-
01-701-1317 / 68/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ CYST/ CYST	- (-) / Ongoing (.)	Mild	3	None	-
01-701-1317 / 68/W/M	INFECTIONS AND INFESTATIONS/ ONYCHOMYCOSIS/ ONYCHOMYCOSIS	- (-) / Ongoing (.)	Mild	3	None	-
01-701-1317 / 68/W/M	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS/ DYSPHONIA/ DYSPHONIA	- (-) / Ongoing (.)	Mild	3	Remote	-
01-701-1317 / 68/W/M	PSYCHIATRIC DISORDERS/ DEPRESSED MOOD/ DEPRESSED MOOD	- (-) / Ongoing (.)	Mild	3	Possible	-
01-701-1317 / 68/W/M	PSYCHIATRIC DISORDERS/ DEPRESSED MOOD/ DEPRESSED MOOD	- (-) / Ongoing (.)	Moderate	3	Possible	-
01-701-1324 / 79/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE ERYTHEMA/ APPLICATION SITE ERYTHEMA	- (-) / Ongoing (.)	Mild	3	Probable	-
01-701-1324 / 79/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline Low Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-701-1324 / 79/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE VESICLES/ APPLICATION SITE VESICLES	- (-) / Ongoing (.)	Mild	3	Probable	-
01-701-1324 / 79/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE VESICLES/ APPLICATION SITE VESICLES	- (-) / Ongoing (.)	Mild	1	Probable	-
01-701-1341 / 51/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE ERYTHEMA/ APPLICATION SITE ERYTHEMA	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-701-1341 / 51/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE ERYTHEMA/ APPLICATION SITE ERYTHEMA	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-701-1341 / 51/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-701-1341 / 51/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Moderate	1	Probable	-
01-701-1341 / 51/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE IRRITATION/ APPLICATION SITE IRRITATION	- (-) / Ongoing (.)	Moderate	1	Probable	-
01-701-1442 / 57/B/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-

Copyright © DH

**Adverse Events
Safety Analysis Set**

Xanomeline Low Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-702-1082 / 84/W/F	GASTROINTESTINAL DISORDERS/ RECTAL HAEMORRHAGE/ RECTAL HAEMORRHAGE	- (-) / Ongoing (.)	Mild	3	None	-
01-702-1082 / 84/W/F	GASTROINTESTINAL DISORDERS/ RECTAL HAEMORRHAGE/ RECTAL HAEMORRHAGE	- (-) / Ongoing (.)	Mild	1	None	-
01-702-1082 / 84/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE IRRITATION/ APPLICATION SITE IRRITATION	- (-) / Ongoing (.)	Mild	1	Probable	-
01-702-1082 / 84/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ SKIN IRRITATION/ SKIN IRRITATION	- (-) / Ongoing (.)	Moderate	1	Probable	-
01-702-1082 / 84/W/F	INVESTIGATIONS/ NEUTROPHIL COUNT INCREASED/ NEUTROPHIL COUNT INCREASED	- (-) / Ongoing (.)	Mild	3	None	-
01-702-1082 / 84/W/F	INVESTIGATIONS/ NEUTROPHIL COUNT INCREASED/ NEUTROPHIL COUNT INCREASED	- (-) / Ongoing (.)	Mild	1	None	-
01-702-1082 / 84/W/F	INVESTIGATIONS/ URINE ANALYSIS ABNORMAL/ URINE ANALYSIS ABNORMAL	- (-) / Ongoing (.)	Mild	3	None	-
01-702-1082 / 84/W/F	INVESTIGATIONS/ URINE ANALYSIS ABNORMAL/ URINE ANALYSIS ABNORMAL	- (-) / Ongoing (.)	Mild	1	None	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline Low Dose

Subject ID/ Age/Race/Se x	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-702-1082 / 84/W/F	INVESTIGATIONS/ WHITE BLOOD CELL COUNT INCREASED/ WHITE BLOOD CELL COUNT INCREASED	- (-) / Ongoing (.)	Mild	3	None	-
01-702-1082 / 84/W/F	INVESTIGATIONS/ WHITE BLOOD CELL COUNT INCREASED/ WHITE BLOOD CELL COUNT INCREASED	- (-) / Ongoing (.)	Mild	1	None	-
01-703-1086 / 71/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE IRRITATION/ APPLICATION SITE IRRITATION	- (-) / Ongoing (.)	Mild	3	Probable	-
01-703-1086 / 71/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE IRRITATION/ APPLICATION SITE IRRITATION	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-703-1086 / 71/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE IRRITATION/ APPLICATION SITE IRRITATION	- (-) / Ongoing (.)	Severe	3	Probable	-
01-703-1086 / 71/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE IRRITATION/ APPLICATION SITE IRRITATION	- (-) / Ongoing (.)	Mild	1	Probable	-
01-703-1086 / 71/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ CHILLS/ CHILLS	- (-) / Ongoing (.)	Mild	3	Possible	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline Low Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-703-1086 / 71/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ CHILLS/ CHILLS	- (-) / Ongoing (.)	Mild	1	Possible	-
01-703-1119 / 81/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE IRRITATION/ APPLICATION SITE IRRITATION	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-703-1119 / 81/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE IRRITATION/ APPLICATION SITE IRRITATION	- (-) / Ongoing (.)	Severe	3	Probable	-
01-703-1119 / 81/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-703-1119 / 81/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Severe	3	Probable	-
01-703-1182 / 84/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE ERYTHEMA/ APPLICATION SITE ERYTHEMA	- (-) / Ongoing (.)	Mild	3	Possible	-
01-703-1182 / 84/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE ERYTHEMA/ APPLICATION SITE ERYTHEMA	- (-) / Ongoing (.)	Moderate	3	Possible	-
01-703-1182 / 84/W/M	NERVOUS SYSTEM DISORDERS/ SOMNOLENCE/ SOMNOLENCE	- (-) / Ongoing (.)	Mild	3	Remote	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline Low Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-703-1182 / 84/W/M	NERVOUS SYSTEM DISORDERS/ SOMNOLENCE/ SOMNOLENCE	- (-) / Ongoing (.)	Moderate	3	Remote	-
01-704-1009 / 83/W/M	GASTROINTESTINAL DISORDERS/ NAUSEA/ NAUSEA	- (-) / Ongoing (.)	Mild	1	Possible	-
01-704-1009 / 83/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ FATIGUE/ FATIGUE	- (-) / Ongoing (.)	Mild	3	Remote	-
01-704-1009 / 83/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ MALAISE/ MALAISE	- (-) / Ongoing (.)	Mild	3	Possible	-
01-704-1009 / 83/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ MALAISE/ MALAISE	- (-) / Ongoing (.)	Mild	1	Possible	-
01-704-1009 / 83/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH/ RASH	- (-) / Ongoing (.)	Mild	3	Possible	-
01-704-1009 / 83/W/M	NERVOUS SYSTEM DISORDERS/ DIZZINESS/ DIZZINESS	- (-) / Ongoing (.)	Mild	3	Remote	-
01-704-1025 / 81/W/F	CARDIAC DISORDERS/ PALPITATIONS/ PALPITATIONS	- (-) / Ongoing (.)	Moderate	1	Remote	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline Low Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-704-1025 / 81/W/F	CARDIAC DISORDERS/ WOLFF-PARKINSON-WHITE SYNDROME/ WOLFF-PARKINSON-WHITE SYNDROME	- (-) / Ongoing (.)	Mild	3	Possible	-
01-704-1025 / 81/W/F	CARDIAC DISORDERS/ WOLFF-PARKINSON-WHITE SYNDROME/ WOLFF-PARKINSON-WHITE SYNDROME	- (-) / Ongoing (.)	Mild	1	Possible	-
01-704-1025 / 81/W/F	INVESTIGATIONS/ ELECTROCARDIOGRAM ST SEGMENT DEPRESSION/ ELECTROCARDIOGRAM ST SEGMENT DEPRESSION	- (-) / Ongoing (.)	Mild	3	Possible	-
01-704-1025 / 81/W/F	INVESTIGATIONS/ ELECTROCARDIOGRAM ST SEGMENT DEPRESSION/ ELECTROCARDIOGRAM ST SEGMENT DEPRESSION	- (-) / Ongoing (.)	Mild	1	Possible	-
01-704-1025 / 81/W/F	EAR AND LABYRINTH DISORDERS/ VERTIGO/ VERTIGO	- (-) / Ongoing (.)	Moderate	1	Possible	-
01-704-1114 / 77/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ OEDEMA/ OEDEMA	- (-) / Ongoing (.)	Mild	3	Probable	-
01-704-1114 / 77/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Mild	1	Probable	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline Low Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-704-1114 / 77/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-
01-704-1114 / 77/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH/ RASH	- (-) / Ongoing (.)	Mild	3	Probable	-
01-704-1114 / 77/W/M	INFECTIONS AND INFESTATIONS/ INFLUENZA/ INFLUENZA	- (-) / Ongoing (.)	Mild	1	None	-
01-704-1120 / 71/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-
01-704-1120 / 71/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-704-1120 / 71/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH/ RASH	- (-) / Ongoing (.)	Mild	3	Probable	-
01-704-1120 / 71/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH/ RASH	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-704-1120 / 71/W/F	INFECTIONS AND INFESTATIONS/ NASOPHARYNGITIS/ NASOPHARYNGITIS	- (-) / Ongoing (.)	Mild	3	None	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline Low Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-704-1120 / 71/W/F	INFECTIONS AND INFESTATIONS/ NASOPHARYNGITIS/ NASOPHARYNGITIS	- (-) / Ongoing (.)	Mild	1	None	-
01-704-1135 / 74/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH/ RASH	- (-) / Ongoing (.)	Mild	3		-
01-704-1135 / 74/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH/ RASH	- (-) / Ongoing (.)	Severe	3		-
01-704-1218 / 81/W/F	INVESTIGATIONS/ BLOOD GLUCOSE INCREASED/ BLOOD GLUCOSE INCREASED	- (-) / Ongoing (.)	Mild	3	None	-
01-704-1323 / 68/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ OEDEMA/ OEDEMA	- (-) / Ongoing (.)	Mild	3	Probable	-
01-704-1323 / 68/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-
01-704-1323 / 68/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH/ RASH	- (-) / Ongoing (.)	Mild	3	Probable	-
01-704-1323 / 68/W/F	INFECTIONS AND INFESTATIONS/ VIRAL INFECTION/ VIRAL INFECTION	- (-) / Ongoing (.)	Mild	1	None	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline Low Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-704-1325 / 81/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-
01-704-1325 / 81/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH/ RASH	- (-) / Ongoing (.)	Mild	3	Probable	-
01-705-1031 / 56/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH/ RASH	- (-) / Ongoing (.)	Mild	3	Possible	-
01-705-1199 / 87/W/M	GASTROINTESTINAL DISORDERS/ DYSPEPSIA/ DYSPEPSIA	- (-) / Ongoing (.)	Moderate	3	Possible	-
01-705-1199 / 87/W/M	GASTROINTESTINAL DISORDERS/ DYSPEPSIA/ DYSPEPSIA	- (-) / Ongoing (.)	Moderate	1	Possible	-
01-705-1292 / 60/B/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-705-1292 / 60/B/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-
01-705-1393 / 84/W/F	GASTROINTESTINAL DISORDERS/ ABDOMINAL PAIN/ ABDOMINAL PAIN	- (-) / Ongoing (.)	Mild	1	Remote	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline Low Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-705-1393 / 84/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-
01-705-1393 / 84/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Mild	1	Probable	-
01-705-1393 / 84/W/F	NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS) / COLON CANCER/ COLON CANCER	- (-) / Ongoing (.)	Severe	1	None	-
01-705-1431 / 68/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH ERYTHEMATOUS/ RASH ERYTHEMATOUS	- (-) / Ongoing (.)	Mild	3	Probable	-
01-705-1431 / 68/W/F	PSYCHIATRIC DISORDERS/ ANXIETY/ ANXIETY	- (-) / Ongoing (.)	Mild	1	Possible	-
01-706-1384 / 74/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Moderate	3	None	-
01-706-1384 / 74/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-706-1384 / 74/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Moderate	1	None	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline Low Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-706-1384 / 74/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Moderate	1	Probable	-
01-706-1384 / 74/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Moderate	3	None	-
01-706-1384 / 74/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-706-1384 / 74/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Moderate	1	None	-
01-706-1384 / 74/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Moderate	1	Probable	-
01-706-1384 / 74/W/F	INJURY, POISONING AND PROCEDURAL COMPLICATIONS/ EXCORIATION/ EXCORIATION	- (-) / Ongoing (.)	Moderate	3	None	-
01-706-1384 / 74/W/F	INJURY, POISONING AND PROCEDURAL COMPLICATIONS/ EXCORIATION/ EXCORIATION	- (-) / Ongoing (.)	Moderate	1	None	-
01-708-1019 / 68/W/M	EYE DISORDERS/ VISION BLURRED/ VISION BLURRED	- (-) / Ongoing (.)	Mild	1	Possible	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline Low Dose

Subject ID/ Age/Race/Se x	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-708-1019 / 68/W/M	NERVOUS SYSTEM DISORDERS/ HEADACHE/ HEADACHE	- (-) / Ongoing (.)	Severe	1	Possible	-
01-708-1019 / 68/W/M	NERVOUS SYSTEM DISORDERS/ DIZZINESS/ DIZZINESS	- (-) / Ongoing (.)	Mild	1	Possible	-
01-708-1019 / 68/W/M	NERVOUS SYSTEM DISORDERS/ STUPOR/ STUPOR	- (-) / Ongoing (.)	Severe	1	Possible	-
01-708-1019 / 68/W/M	NERVOUS SYSTEM DISORDERS/ TRANSIENT ISCHAEMIC ATTACK/ TRANSIENT ISCHAEMIC ATTACK	- (-) / Ongoing (.)	Severe	1	Possible	-
01-708-1032 / 62/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE VESICLES/ APPLICATION SITE VESICLES	- (-) / Ongoing (.)	Moderate	1	Probable	-
01-708-1084 / 73/W/F	CARDIAC DISORDERS/ MYOCARDIAL INFARCTION/ MYOCARDIAL INFARCTION	- (-) / Ongoing (.)	Mild	3	Remote	-
01-708-1084 / 73/W/F	CARDIAC DISORDERS/ MYOCARDIAL INFARCTION/ MYOCARDIAL INFARCTION	- (-) / Ongoing (.)	Mild	1	Remote	-
01-708-1084 / 73/W/F	CARDIAC DISORDERS/ SINUS BRADYCARDIA/ SINUS BRADYCARDIA	- (-) / Ongoing (.)	Mild	3	Remote	-
01-708-1084 / 73/W/F	CARDIAC DISORDERS/ SINUS BRADYCARDIA/ SINUS BRADYCARDIA	- (-) / Ongoing (.)	Mild	1	Remote	-

Copyright © DH

**Adverse Events
Safety Analysis Set**

Xanomeline Low Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-708-1084 / 73/W/F	NERVOUS SYSTEM DISORDERS/ DIZZINESS/ DIZZINESS	- (-) / Ongoing (.)	Mild	3	Possible	-
01-708-1084 / 73/W/F	NERVOUS SYSTEM DISORDERS/ DIZZINESS/ DIZZINESS	- (-) / Ongoing (.)	Mild	1	Possible	-
01-708-1272 / 82/W/M	GASTROINTESTINAL DISORDERS/ DIARRHOEA/ DIARRHOEA	- (-) / Ongoing (.)	Mild	1	None	-
01-708-1272 / 82/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE DERMATITIS/ APPLICATION SITE DERMATITIS	- (-) / Ongoing (.)	Mild	1	Probable	-
01-708-1272 / 82/W/M	CARDIAC DISORDERS/ VENTRICULAR EXTRASYSTOLES/ VENTRICULAR EXTRASYSTOLES	- (-) / Ongoing (.)	Mild	3	Remote	-
01-708-1272 / 82/W/M	CARDIAC DISORDERS/ VENTRICULAR EXTRASYSTOLES/ VENTRICULAR EXTRASYSTOLES	- (-) / Ongoing (.)	Mild	1	Remote	-
01-708-1272 / 82/W/M	INFECTIONS AND INFESTATIONS/ NASOPHARYNGITIS/ NASOPHARYNGITIS	- (-) / Ongoing (.)	Mild	3	None	-
01-708-1272 / 82/W/M	INFECTIONS AND INFESTATIONS/ NASOPHARYNGITIS/ NASOPHARYNGITIS	- (-) / Ongoing (.)	Mild	1	None	-
01-708-1272 / 82/W/M	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS/ COUGH/ COUGH	- (-) / Ongoing (.)	Mild	3	None	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline Low Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-708-1272 / 82/W/M	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS/ COUGH/ COUGH	- (-) / Ongoing (.)	Mild	1	None	-
01-708-1272 / 82/W/M	MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS/ MUSCLE SPASMS/ MUSCLE SPASMS	- (-) / Ongoing (.)	Severe	1	None	-
01-708-1272 / 82/W/M	NERVOUS SYSTEM DISORDERS/ HEADACHE/ HEADACHE	- (-) / Ongoing (.)	Mild	3	None	-
01-708-1272 / 82/W/M	NERVOUS SYSTEM DISORDERS/ HEADACHE/ HEADACHE	- (-) / Ongoing (.)	Mild	1	None	-
01-708-1272 / 82/W/M	VASCULAR DISORDERS/ HOT FLUSH/ HOT FLUSH	- (-) / Ongoing (.)	Mild	1	None	-
01-708-1297 / 61/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-
01-708-1297 / 61/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE SWELLING/ APPLICATION SITE SWELLING	- (-) / Ongoing (.)	Mild	3	Probable	-
01-708-1297 / 61/W/M	CARDIAC DISORDERS/ SINUS BRADYCARDIA/ SINUS BRADYCARDIA	- (-) / Ongoing (.)	Mild	3	Remote	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline Low Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-708-1348 / 79/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-
01-708-1348 / 79/W/F	CARDIAC DISORDERS/ MYOCARDIAL INFARCTION/ MYOCARDIAL INFARCTION	- (-) / Ongoing (.)	Mild	3	Possible	-
01-708-1348 / 79/W/F	CARDIAC DISORDERS/ MYOCARDIAL INFARCTION/ MYOCARDIAL INFARCTION	- (-) / Ongoing (.)	Mild	1	Possible	-
01-708-1353 / 87/B/F	NERVOUS SYSTEM DISORDERS/ DIZZINESS/ DIZZINESS	- (-) / Ongoing (.)	Mild	3	Remote	-
01-708-1353 / 87/B/F	NERVOUS SYSTEM DISORDERS/ DIZZINESS/ DIZZINESS	- (-) / Ongoing (.)	Mild	1	Remote	-
01-708-1353 / 87/B/F	VASCULAR DISORDERS/ HYPOTENSION/ HYPOTENSION	- (-) / Ongoing (.)	Mild	1	Possible	-
01-708-1428 / 84/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE ERYTHEMA/ APPLICATION SITE ERYTHEMA	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-708-1428 / 84/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE ERYTHEMA/ APPLICATION SITE ERYTHEMA	- (-) / Ongoing (.)	Severe	1	Probable	-
01-708-1428 / 84/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Moderate	3	Probable	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline Low Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-708-1428 / 84/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Severe	1	Probable	-
01-708-1428 / 84/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE WARMTH/ APPLICATION SITE WARMTH	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-708-1428 / 84/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE WARMTH/ APPLICATION SITE WARMTH	- (-) / Ongoing (.)	Severe	1	Probable	-
01-708-1428 / 84/W/F	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS/ EPISTAXIS/ EPISTAXIS	- (-) / Ongoing (.)	Mild	1	Remote	-
01-709-1007 / 54/W/F	GASTROINTESTINAL DISORDERS/ DIARRHOEA/ DIARRHOEA	- (-) / Ongoing (.)	Mild	1	Possible	-
01-709-1007 / 54/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE DERMATITIS/ APPLICATION SITE DERMATITIS	- (-) / Ongoing (.)	Mild	3	Probable	-
01-709-1007 / 54/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE DERMATITIS/ APPLICATION SITE DERMATITIS	- (-) / Ongoing (.)	Mild	1	Probable	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline Low Dose

Subject ID/ Age/Race/Se x	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-709-1007 / 54/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE DERMATITIS/ APPLICATION SITE DERMATITIS	- (-) / Ongoing (.)	Severe	3	Probable	-
01-709-1020 / 72/W/F	GASTROINTESTINAL DISORDERS/ DIARRHOEA/ DIARRHOEA	- (-) / Ongoing (.)	Mild	1	Possible	-
01-709-1020 / 72/W/F	GASTROINTESTINAL DISORDERS/ ABDOMINAL PAIN/ ABDOMINAL PAIN	- (-) / Ongoing (.)	Mild	1	Possible	-
01-709-1020 / 72/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-
01-709-1020 / 72/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE DERMATITIS/ APPLICATION SITE DERMATITIS	- (-) / Ongoing (.)	Mild	3	Probable	-
01-709-1081 / 86/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ OEDEMA PERIPHERAL/ OEDEMA PERIPHERAL	- (-) / Ongoing (.)	Moderate	3	Remote	-
01-709-1081 / 86/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH/ RASH	- (-) / Ongoing (.)	Moderate	3	Probable	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline Low Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-709-1102 / 71/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-
01-709-1102 / 71/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-709-1102 / 71/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE VESICLES/ APPLICATION SITE VESICLES	- (-) / Ongoing (.)	Mild	1	Probable	-
01-709-1102 / 71/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE DERMATITIS/ APPLICATION SITE DERMATITIS	- (-) / Ongoing (.)	Mild	3	Probable	-
01-709-1102 / 71/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE DERMATITIS/ APPLICATION SITE DERMATITIS	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-709-1102 / 71/W/F	NERVOUS SYSTEM DISORDERS/ DIZZINESS/ DIZZINESS	- (-) / Ongoing (.)	Mild	1	Possible	-
01-709-1217 / 77/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE DERMATITIS/ APPLICATION SITE DERMATITIS	- (-) / Ongoing (.)	Mild	3	Probable	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline Low Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-709-1217 / 77/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE DERMATITIS/ APPLICATION SITE DERMATITIS	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-709-1217 / 77/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE DERMATITIS/ APPLICATION SITE DERMATITIS	- (-) / Ongoing (.)	Moderate	1	Probable	-
01-709-1217 / 77/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Moderate	1	Probable	-
01-709-1217 / 77/W/M	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS/ COUGH/ COUGH	- (-) / Ongoing (.)	Mild	3	None	-
01-709-1217 / 77/W/M	NERVOUS SYSTEM DISORDERS/ HEADACHE/ HEADACHE	- (-) / Ongoing (.)	Mild	1	Remote	-
01-709-1217 / 77/W/M	NERVOUS SYSTEM DISORDERS/ DIZZINESS/ DIZZINESS	- (-) / Ongoing (.)	Moderate	1	Possible	-
01-709-1217 / 77/W/M	NERVOUS SYSTEM DISORDERS/ DIZZINESS/ DIZZINESS	- (-) / Ongoing (.)	Mild	1	Possible	-
01-709-1217 / 77/W/M	NERVOUS SYSTEM DISORDERS/ DIZZINESS/ DIZZINESS	- (-) / Ongoing (.)	Mild	3	Possible	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline Low Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-709-1217 / 77/W/M	NERVOUS SYSTEM DISORDERS/ DIZZINESS/ DIZZINESS	- (-) / Ongoing (.)	Mild	1	Possible	-
01-709-1217 / 77/W/M	INVESTIGATIONS/ ELECTROCARDIOGRAM T WAVE INVERSION/ ELECTROCARDIOGRAM T WAVE INVERSION	- (-) / Ongoing (.)	Mild	3	None	-
01-709-1285 / 87/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-
01-709-1285 / 87/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Mild	1	Probable	-
01-709-1285 / 87/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE DERMATITIS/ APPLICATION SITE DERMATITIS	- (-) / Ongoing (.)	Mild	3	Probable	-
01-709-1285 / 87/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE DERMATITIS/ APPLICATION SITE DERMATITIS	- (-) / Ongoing (.)	Mild	1	Probable	-
01-709-1285 / 87/W/M	CARDIAC DISORDERS/ SINUS BRADYCARDIA/ SINUS BRADYCARDIA	- (-) / Ongoing (.)	Mild	3	Possible	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline Low Dose

Subject ID/ Age/Race/Se x	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-709-1285 / 87/W/M	NERVOUS SYSTEM DISORDERS/ HEMIANOPIA HOMONYMOUS/ HEMIANOPIA HOMONYMOUS	- (-) / Ongoing (.)	Mild	3	None	-
01-709-1326 / 75/W/F	GASTROINTESTINAL DISORDERS/ VOMITING/ VOMITING	- (-) / Ongoing (.)	Mild	1	Possible	-
01-709-1326 / 75/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-
01-709-1326 / 75/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE DERMATITIS/ APPLICATION SITE DERMATITIS	- (-) / Ongoing (.)	Mild	3	Probable	-
01-709-1326 / 75/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE BLEEDING/ APPLICATION SITE BLEEDING	- (-) / Ongoing (.)	Moderate	1	Probable	-
01-709-1326 / 75/W/F	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS/ COUGH/ COUGH	- (-) / Ongoing (.)	Mild	3	None	-
01-709-1326 / 75/W/F	NERVOUS SYSTEM DISORDERS/ SYNCOPE/ SYNCOPE	- (-) / Ongoing (.)	Mild	1	Possible	-
01-710-1002 / 88/W/M	NERVOUS SYSTEM DISORDERS/ TRANSIENT ISCHAEMIC ATTACK/ TRANSIENT ISCHAEMIC ATTACK	- (-) / Ongoing (.)	Mild	3	Remote	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline Low Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-710-1002 / 88/W/M	NERVOUS SYSTEM DISORDERS/ TRANSIENT ISCHAEMIC ATTACK/ TRANSIENT ISCHAEMIC ATTACK	- (-) / Ongoing (.)	Mild	1	Remote	-
01-710-1045 / 83/W/F	GASTROINTESTINAL DISORDERS/ VOMITING/ VOMITING	- (-) / Ongoing (.)	Mild	1	Remote	-
01-710-1045 / 83/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Mild	3	Possible	-
01-710-1045 / 83/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Mild	1	Possible	-
01-710-1045 / 83/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Mild	3	Possible	-
01-710-1045 / 83/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Mild	1	Possible	-
01-710-1045 / 83/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH/ RASH	- (-) / Ongoing (.)	Mild	3	Possible	-
01-710-1045 / 83/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH/ RASH	- (-) / Ongoing (.)	Mild	1	Possible	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline Low Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-710-1045 / 83/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ SKIN IRRITATION/ SKIN IRRITATION	- (-) / Ongoing (.)	Mild	3	Possible	-
01-710-1045 / 83/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ SKIN IRRITATION/ SKIN IRRITATION	- (-) / Ongoing (.)	Mild	1	Possible	-
01-710-1045 / 83/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ SKIN EXFOLIATION/ SKIN EXFOLIATION	- (-) / Ongoing (.)	Moderate	3	Possible	-
01-710-1045 / 83/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ SKIN EXFOLIATION/ SKIN EXFOLIATION	- (-) / Ongoing (.)	Moderate	1	Possible	-
01-710-1045 / 83/W/F	INFECTIONS AND INFESTATIONS/ NASOPHARYNGITIS/ NASOPHARYNGITIS	- (-) / Ongoing (.)	Mild	3	None	-
01-710-1045 / 83/W/F	INFECTIONS AND INFESTATIONS/ NASOPHARYNGITIS/ NASOPHARYNGITIS	- (-) / Ongoing (.)	Mild	1	None	-
01-710-1053 / 84/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Moderate	3	Possible	-
01-710-1053 / 84/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Moderate	1	Possible	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline Low Dose

Subject ID/ Age/Race/Se x	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-710-1053 / 84/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH/ RASH	- (-) / Ongoing (.)	Moderate	3	Possible	-
01-710-1053 / 84/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH/ RASH	- (-) / Ongoing (.)	Moderate	1	Possible	-
01-710-1154 / 84/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ SKIN IRRITATION/ SKIN IRRITATION	- (-) / Ongoing (.)	Moderate	3	Possible	-
01-710-1154 / 84/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ SKIN IRRITATION/ SKIN IRRITATION	- (-) / Ongoing (.)	Severe	3	Possible	-
01-710-1166 / 81/W/F	NERVOUS SYSTEM DISORDERS/ SYNCOPE/ SYNCOPE	- (-) / Ongoing (.)	Moderate	1	Possible	-
01-710-1166 / 81/W/F	NERVOUS SYSTEM DISORDERS/ SYNCOPE/ SYNCOPE	- (-) / Ongoing (.)	Moderate	1	Possible	-
01-710-1166 / 81/W/F	NERVOUS SYSTEM DISORDERS/ COMPLEX PARTIAL SEIZURES/ COMPLEX PARTIAL SEIZURES	- (-) / Ongoing (.)	Moderate	1	Possible	-
01-710-1166 / 81/W/F	INJURY, POISONING AND PROCEDURAL COMPLICATIONS/ SKIN LACERATION/ SKIN LACERATION	- (-) / Ongoing (.)	Moderate	1	Possible	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline Low Dose

Subject ID/ Age/Race/Se x	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-710-1166 / 81/W/F	INJURY, POISONING AND PROCEDURAL COMPLICATIONS/ FALL/ FALL	- (-) / Ongoing (.)	Moderate	1	Possible	-
01-710-1235 / 56/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Mild	3	Possible	-
01-710-1235 / 56/W/F	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS/ COUGH/ COUGH	- (-) / Ongoing (.)	Moderate	1	None	-
01-710-1235 / 56/W/F	MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS/ SHOULDER PAIN/ SHOULDER PAIN	- (-) / Ongoing (.)	Mild	3	None	-
01-710-1270 / 83/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Moderate	3	Possible	-
01-710-1270 / 83/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Moderate	3	Possible	-
01-710-1300 / 78/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE IRRITATION/ APPLICATION SITE IRRITATION	- (-) / Ongoing (.)	Mild	3	Possible	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline Low Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-710-1300 / 78/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Moderate	3	Possible	-
01-710-1300 / 78/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Moderate	3	Possible	-
01-710-1300 / 78/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ BLISTER/ BLISTER	- (-) / Ongoing (.)	Moderate	3	Possible	-
01-710-1358 / 82/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE DESQUAMATION/ APPLICATION SITE DESQUAMATION	- (-) / Ongoing (.)	Mild	3	Possible	-
01-710-1358 / 82/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Mild	3	Possible	-
01-710-1358 / 82/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH/ RASH	- (-) / Ongoing (.)	Mild	3	Possible	-
01-710-1385 / 77/W/M	CARDIAC DISORDERS/ ATRIOVENTRICULAR BLOCK FIRST DEGREE/ ATRIOVENTRICULAR BLOCK FIRST DEGREE	- (-) / Ongoing (.)	Mild	3	None	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline Low Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-710-1385 / 77/W/M	CARDIAC DISORDERS/ ATRIAL FIBRILLATION/ ATRIAL FIBRILLATION	- (-) / Ongoing (.)	Moderate	3	None	-
01-710-1385 / 77/W/M	CARDIAC DISORDERS/ SUPRAVENTRICULAR TACHYCARDIA/ SUPRAVENTRICULAR TACHYCARDIA	- (-) / Ongoing (.)	Moderate	3	None	-
01-710-1385 / 77/W/M	CARDIAC DISORDERS/ SUPRAVENTRICULAR TACHYCARDIA/ SUPRAVENTRICULAR TACHYCARDIA	- (-) / Ongoing (.)	Moderate	1	None	-
01-710-1385 / 77/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Mild	3	Possible	-
01-710-1385 / 77/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH/ RASH	- (-) / Ongoing (.)	Mild	3	Possible	-
01-710-1385 / 77/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ BLISTER/ BLISTER	- (-) / Ongoing (.)	Mild	3	Possible	-
01-710-1385 / 77/W/M	INVESTIGATIONS/ ELECTROCARDIOGRAM T WAVE AMPLITUDE DECREASED/ ELECTROCARDIOGRAM T WAVE AMPLITUDE DECREASED	- (-) / Ongoing (.)	Mild	3	Remote	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline Low Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-711-1143 / 76/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE DERMATITIS/ APPLICATION SITE DERMATITIS	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-711-1143 / 76/W/F	CARDIAC DISORDERS/ SUPRAVENTRICULAR EXTRASYSTOLES/ SUPRAVENTRICULAR EXTRASYSTOLES	- (-) / Ongoing (.)	Mild	3	Possible	-
01-711-1143 / 76/W/F	CARDIAC DISORDERS/ SUPRAVENTRICULAR EXTRASYSTOLES/ SUPRAVENTRICULAR EXTRASYSTOLES	- (-) / Ongoing (.)	Mild	1	Possible	-
01-711-1143 / 76/W/F	CARDIAC DISORDERS/ VENTRICULAR EXTRASYSTOLES/ VENTRICULAR EXTRASYSTOLES	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-711-1143 / 76/W/F	CARDIAC DISORDERS/ VENTRICULAR EXTRASYSTOLES/ VENTRICULAR EXTRASYSTOLES	- (-) / Ongoing (.)	Moderate	1	Probable	-
01-711-1143 / 76/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH PRURITIC/ RASH PRURITIC	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-711-1143 / 76/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH PRURITIC/ RASH PRURITIC	- (-) / Ongoing (.)	Moderate	1	Probable	-
01-711-1143 / 76/W/F	INFECTIONS AND INFESTATIONS/ NASOPHARYNGITIS/ NASOPHARYNGITIS	- (-) / Ongoing (.)	Severe	3	None	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline Low Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-711-1143 / 76/W/F	INFECTIONS AND INFESTATIONS/ NASOPHARYNGITIS/ NASOPHARYNGITIS	- (-) / Ongoing (.)	Mild	3	None	-
01-711-1143 / 76/W/F	INFECTIONS AND INFESTATIONS/ NASOPHARYNGITIS/ NASOPHARYNGITIS	- (-) / Ongoing (.)	Mild	1	None	-
01-711-1143 / 76/W/F	EYE DISORDERS/ CONJUNCTIVAL HAEMORRHAGE/ CONJUNCTIVAL HAEMORRHAGE	- (-) / Ongoing (.)	Moderate	3	Remote	-
01-711-1143 / 76/W/F	NERVOUS SYSTEM DISORDERS/ PARAESTHESIA ORAL/ PARAESTHESIA ORAL	- (-) / Ongoing (.)	Mild	3	Possible	-
01-711-1143 / 76/W/F	EAR AND LABYRINTH DISORDERS/ CERUMEN IMPACTION/ CERUMEN IMPACTION	- (-) / Ongoing (.)	Mild	3	None	-
01-711-1143 / 76/W/F	EAR AND LABYRINTH DISORDERS/ TINNITUS/ TINNITUS	- (-) / Ongoing (.)	Moderate	3	Possible	-
01-713-1043 / 78/W/F	GASTROINTESTINAL DISORDERS/ NAUSEA/ NAUSEA	- (-) / Ongoing (.)	Moderate	3	Possible	-
01-713-1043 / 78/W/F	GASTROINTESTINAL DISORDERS/ NAUSEA/ NAUSEA	- (-) / Ongoing (.)	Moderate	1	Possible	-
01-713-1043 / 78/W/F	GASTROINTESTINAL DISORDERS/ VOMITING/ VOMITING	- (-) / Ongoing (.)	Moderate	3	Possible	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline Low Dose

Subject ID/ Age/Race/Se x	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-713-1043 / 78/W/F	GASTROINTESTINAL DISORDERS/ VOMITING/ VOMITING	- (-) / Ongoing (.)	Moderate	1	Possible	-
01-713-1043 / 78/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE ERYTHEMA/ APPLICATION SITE ERYTHEMA	- (-) / Ongoing (.)	Mild	3	Probable	-
01-713-1043 / 78/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE ERYTHEMA/ APPLICATION SITE ERYTHEMA	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-713-1043 / 78/W/F	SURGICAL AND MEDICAL PROCEDURES/ CATARACT OPERATION/ CATARACT OPERATION	- (-) / Ongoing (.)	Mild	1	None	-
01-713-1073 / 74/B/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-
01-713-1448 / 71/W/F	GASTROINTESTINAL DISORDERS/ NAUSEA/ NAUSEA	- (-) / Ongoing (.)	Mild	3	Possible	-
01-713-1448 / 71/W/F	GASTROINTESTINAL DISORDERS/ NAUSEA/ NAUSEA	- (-) / Ongoing (.)	Mild	1	Possible	-
01-713-1448 / 71/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE IRRITATION/ APPLICATION SITE IRRITATION	- (-) / Ongoing (.)	Moderate	3	Probable	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline Low Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-713-1448 / 71/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE IRRITATION/ APPLICATION SITE IRRITATION	- (-) / Ongoing (.)	Moderate	1	Probable	-
01-714-1068 / 79/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE ERYTHEMA/ APPLICATION SITE ERYTHEMA	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-714-1068 / 79/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE ERYTHEMA/ APPLICATION SITE ERYTHEMA	- (-) / Ongoing (.)	Mild	3	Probable	-
01-714-1068 / 79/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-714-1068 / 79/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-
01-714-1068 / 79/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ SKIN IRRITATION/ SKIN IRRITATION	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-714-1068 / 79/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ SKIN IRRITATION/ SKIN IRRITATION	- (-) / Ongoing (.)	Moderate	1	Probable	-
01-714-1195 / 75/W/M	GASTROINTESTINAL DISORDERS/ DIARRHOEA/ DIARRHOEA	- (-) / Ongoing (.)	Mild	3	Remote	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline Low Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-714-1195 / 75/W/M	GASTROINTESTINAL DISORDERS/ DIARRHOEA/ DIARRHOEA	- (-) / Ongoing (.)	Mild	1	Remote	-
01-714-1195 / 75/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE ERYTHEMA/ APPLICATION SITE ERYTHEMA	- (-) / Ongoing (.)	Severe	3	Probable	-
01-714-1195 / 75/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE ERYTHEMA/ APPLICATION SITE ERYTHEMA	- (-) / Ongoing (.)	Severe	1	Probable	-
01-714-1195 / 75/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-
01-714-1195 / 75/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ HYPERHIDROSIS/ HYPERHIDROSIS	- (-) / Ongoing (.)	Moderate	3	Possible	-
01-714-1195 / 75/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ HYPERHIDROSIS/ HYPERHIDROSIS	- (-) / Ongoing (.)	Moderate	1	Possible	-
01-714-1195 / 75/W/M	NERVOUS SYSTEM DISORDERS/ SOMNOLENCE/ SOMNOLENCE	- (-) / Ongoing (.)	Mild	3	None	-
01-714-1195 / 75/W/M	RENAL AND URINARY DISORDERS/ DYSURIA/ DYSURIA	- (-) / Ongoing (.)	Mild	1	Remote	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline Low Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day)/ Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-715-1107 / 65/W/M	CARDIAC DISORDERS/ SINUS BRADYCARDIA/ SINUS BRADYCARDIA	- (-)/ Ongoing (.)	Mild	3	None	-
01-715-1107 / 65/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ DERMATITIS CONTACT/ DERMATITIS CONTACT	- (-)/ Ongoing (.)	Moderate	3	Probable	-
01-715-1107 / 65/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ DERMATITIS CONTACT/ DERMATITIS CONTACT	- (-)/ Ongoing (.)	Moderate	1	Probable	-
01-715-1405 / 69/W/M	CARDIAC DISORDERS/ SINUS BRADYCARDIA/ SINUS BRADYCARDIA	- (-)/ Ongoing (.)	Moderate	3	None	-
01-715-1405 / 69/W/M	CARDIAC DISORDERS/ SINUS BRADYCARDIA/ SINUS BRADYCARDIA	- (-)/ Ongoing (.)	Moderate	1	None	-
01-715-1405 / 69/W/M	CARDIAC DISORDERS/ PALPITATIONS/ PALPITATIONS	- (-)/ Ongoing (.)	Moderate	1	Probable	-
01-715-1405 / 69/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ HYPERHIDROSIS/ HYPERHIDROSIS	- (-)/ Ongoing (.)	Moderate	1	Probable	-
01-715-1405 / 69/W/M	NERVOUS SYSTEM DISORDERS/ DIZZINESS/ DIZZINESS	- (-)/ Ongoing (.)	Moderate	1	Probable	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline Low Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-715-1405 / 69/W/M	PSYCHIATRIC DISORDERS/ CONFUSIONAL STATE/ CONFUSIONAL STATE	- (-) / Ongoing (.)	Moderate	1	Probable	-
01-716-1063 / 80/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ FATIGUE/ FATIGUE	- (-) / Ongoing (.)	Mild	3	Possible	-
01-716-1063 / 80/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-
01-716-1063 / 80/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Mild	1	Probable	-
01-716-1063 / 80/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ HYPERHIDROSIS/ HYPERHIDROSIS	- (-) / Ongoing (.)	Mild	3	Probable	-
01-716-1063 / 80/W/M	NERVOUS SYSTEM DISORDERS/ LETHARGY/ LETHARGY	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-716-1063 / 80/W/M	PSYCHIATRIC DISORDERS/ RESTLESSNESS/ RESTLESSNESS	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-716-1063 / 80/W/M	PSYCHIATRIC DISORDERS/ RESTLESSNESS/ RESTLESSNESS	- (-) / Ongoing (.)	Moderate	1	Probable	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline Low Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-716-1094 / 82/W/M	CARDIAC DISORDERS/ BUNDLE BRANCH BLOCK RIGHT/ BUNDLE BRANCH BLOCK RIGHT	- (-) / Ongoing (.)	Moderate	3	Possible	-
01-716-1094 / 82/W/M	CARDIAC DISORDERS/ ATRIAL FLUTTER/ ATRIAL FLUTTER	- (-) / Ongoing (.)	Moderate	3	Possible	-
01-716-1094 / 82/W/M	CONGENITAL, FAMILIAL AND GENETIC DISORDERS/ VENTRICULAR SEPTAL DEFECT/ VENTRICULAR SEPTAL DEFECT	- (-) / Ongoing (.)	Moderate	3	Possible	-
01-716-1103 / 79/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-716-1103 / 79/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-716-1103 / 79/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ BLISTER/ BLISTER	- (-) / Ongoing (.)	Moderate	1	Probable	-
01-716-1103 / 79/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ BLISTER/ BLISTER	- (-) / Ongoing (.)	Severe	3	Probable	-
01-716-1103 / 79/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ BLISTER/ BLISTER	- (-) / Ongoing (.)	Severe	1	Probable	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline Low Dose

Subject ID/ Age/Race/Se x	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-716-1151 / 83/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-716-1151 / 83/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-716-1151 / 83/W/F	NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS) / MALIGNANT FIBROUS HISTIOCYTOMA/ MALIGNANT FIBROUS HISTIOCYTOMA	- (-) / Ongoing (.)	Mild	3	None	-
01-716-1151 / 83/W/F	NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS) / MALIGNANT FIBROUS HISTIOCYTOMA/ MALIGNANT FIBROUS HISTIOCYTOMA	- (-) / Ongoing (.)	Mild	1	None	-
01-716-1157 / 85/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Mild	3	Probable	-
01-716-1157 / 85/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline Low Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-716-1157 / 85/W/M	INFECTIONS AND INFESTATIONS/ UPPER RESPIRATORY TRACT INFECTION/ UPPER RESPIRATORY TRACT INFECTION	- (-) / Ongoing (.)	Mild	3	None	-
01-716-1157 / 85/W/M	INFECTIONS AND INFESTATIONS/ UPPER RESPIRATORY TRACT INFECTION/ UPPER RESPIRATORY TRACT INFECTION	- (-) / Ongoing (.)	Mild	1	None	-
01-716-1167 / 68/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ SWELLING/ SWELLING	- (-) / Ongoing (.)	Moderate	3	None	-
01-716-1167 / 68/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Moderate	3	None	-
01-716-1167 / 68/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ BLISTER/ BLISTER	- (-) / Ongoing (.)	Moderate	3	Possible	-
01-716-1167 / 68/W/M	IMMUNE SYSTEM DISORDERS/ HYPERSENSITIVITY/ HYPERSENSITIVITY	- (-) / Ongoing (.)	Mild	3	None	-
01-716-1167 / 68/W/M	IMMUNE SYSTEM DISORDERS/ HYPERSENSITIVITY/ HYPERSENSITIVITY	- (-) / Ongoing (.)	Mild	1	None	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline Low Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-716-1298 / 76/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-716-1298 / 76/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Moderate	1	Probable	-
01-716-1298 / 76/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-716-1298 / 76/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Moderate	1	Probable	-
01-716-1298 / 76/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ BLISTER/ BLISTER	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-716-1298 / 76/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ BLISTER/ BLISTER	- (-) / Ongoing (.)	Moderate	1	Probable	-
01-716-1311 / 78/W/M	GASTROINTESTINAL DISORDERS/ ABDOMINAL PAIN/ ABDOMINAL PAIN	- (-) / Ongoing (.)	Moderate	1	None	-
01-716-1311 / 78/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ ULCER/ ULCER	- (-) / Ongoing (.)	Moderate	3	None	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline Low Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-716-1311 / 78/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Mild	3	Probable	-
01-716-1311 / 78/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Mild	1	Probable	-
01-717-1004 / 80/W/F	GASTROINTESTINAL DISORDERS/ DIARRHOEA/ DIARRHOEA	- (-) / Ongoing (.)	Mild	3	Possible	-
01-717-1004 / 80/W/F	GASTROINTESTINAL DISORDERS/ DIARRHOEA/ DIARRHOEA	- (-) / Ongoing (.)	Mild	1	Possible	-
01-717-1004 / 80/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ FATIGUE/ FATIGUE	- (-) / Ongoing (.)	Moderate	3	Possible	-
01-717-1004 / 80/W/F	CARDIAC DISORDERS/ SINUS BRADYCARDIA/ SINUS BRADYCARDIA	- (-) / Ongoing (.)	Mild	3	Possible	-
01-717-1004 / 80/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ SKIN IRRITATION/ SKIN IRRITATION	- (-) / Ongoing (.)	Mild	3	Probable	-
01-717-1004 / 80/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ SKIN IRRITATION/ SKIN IRRITATION	- (-) / Ongoing (.)	Mild	1	Probable	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline Low Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-717-1004 / 80/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ SKIN IRRITATION/ SKIN IRRITATION	- (-) / Ongoing (.)	Mild	3	Probable	-
01-717-1004 / 80/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ SKIN IRRITATION/ SKIN IRRITATION	- (-) / Ongoing (.)	Mild	1	Probable	-
01-717-1004 / 80/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ SKIN IRRITATION/ SKIN IRRITATION	- (-) / Ongoing (.)	Mild	3	Probable	-
01-717-1004 / 80/W/F	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS/ COUGH/ COUGH	- (-) / Ongoing (.)	Moderate	3	Remote	-
01-717-1004 / 80/W/F	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS/ COUGH/ COUGH	- (-) / Ongoing (.)	Moderate	1	Remote	-
01-717-1004 / 80/W/F	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS/ RHINORRHOEA/ RHINORRHOEA	- (-) / Ongoing (.)	Mild	3	Remote	-
01-717-1004 / 80/W/F	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS/ RHINORRHOEA/ RHINORRHOEA	- (-) / Ongoing (.)	Mild	1	Remote	-
01-717-1004 / 80/W/F	MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS/ BACK PAIN/ BACK PAIN	- (-) / Ongoing (.)	Moderate	3	None	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline Low Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-717-1004 / 80/W/F	RENAL AND URINARY DISORDERS/ ENURESIS/ ENURESIS	- (-) / Ongoing (.)	Moderate	3	Possible	-
01-717-1004 / 80/W/F	PSYCHIATRIC DISORDERS/ ANXIETY/ ANXIETY	- (-) / Ongoing (.)	Mild	3	Possible	-
01-717-1004 / 80/W/F	PSYCHIATRIC DISORDERS/ IRRITABILITY/ IRRITABILITY	- (-) / Ongoing (.)	Mild	3	Possible	-
01-717-1004 / 80/W/F	INJURY, POISONING AND PROCEDURAL COMPLICATIONS/ WOUND/ WOUND	- (-) / Ongoing (.)	Mild	3	Probable	-
01-717-1004 / 80/W/F	INJURY, POISONING AND PROCEDURAL COMPLICATIONS/ WOUND/ WOUND	- (-) / Ongoing (.)	Mild	1	Probable	-
01-717-1446 / 75/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ PAIN/ PAIN	- (-) / Ongoing (.)	Moderate	1	Probable	-
01-717-1446 / 75/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ PAIN/ PAIN	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-717-1446 / 75/W/F	CARDIAC DISORDERS/ SINUS BRADYCARDIA/ SINUS BRADYCARDIA	- (-) / Ongoing (.)	Mild	3	Remote	-
01-717-1446 / 75/W/F	CARDIAC DISORDERS/ SINUS BRADYCARDIA/ SINUS BRADYCARDIA	- (-) / Ongoing (.)	Mild	1	Remote	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline Low Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-717-1446 / 75/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH/ RASH	- (-) / Ongoing (.)	Mild	3	Remote	-
01-717-1446 / 75/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH/ RASH	- (-) / Ongoing (.)	Mild	1	Remote	-
01-717-1446 / 75/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ SKIN IRRITATION/ SKIN IRRITATION	- (-) / Ongoing (.)	Moderate	3	Possible	-
01-717-1446 / 75/W/F	PSYCHIATRIC DISORDERS/ ANXIETY/ ANXIETY	- (-) / Ongoing (.)	Mild	3	Possible	-
01-717-1446 / 75/W/F	PSYCHIATRIC DISORDERS/ ANXIETY/ ANXIETY	- (-) / Ongoing (.)	Mild	1	Possible	-
01-718-1066 / 79/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ INFLAMMATION/ INFLAMMATION	- (-) / Ongoing (.)	Moderate	3	Remote	-
01-718-1066 / 79/W/F	NERVOUS SYSTEM DISORDERS/ SYNCOPE/ SYNCOPE	- (-) / Ongoing (.)	Severe	1	Possible	-
01-718-1066 / 79/W/F	NERVOUS SYSTEM DISORDERS/ SYNCOPE/ SYNCOPE	- (-) / Ongoing (.)	Severe	3	Possible	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline Low Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-718-1066 / 79/W/F	PSYCHIATRIC DISORDERS/ AGITATION/ AGITATION	- (-) / Ongoing (.)	Moderate	3	Possible	-
01-718-1079 / 67/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE IRRITATION/ APPLICATION SITE IRRITATION	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-718-1079 / 67/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE IRRITATION/ APPLICATION SITE IRRITATION	- (-) / Ongoing (.)	Severe	3	Probable	-
01-718-1079 / 67/W/F	PSYCHIATRIC DISORDERS/ CONFUSIONAL STATE/ CONFUSIONAL STATE	- (-) / Ongoing (.)	Moderate	3	Possible	-
01-718-1170 / 80/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ HYPERHIDROSIS/ HYPERHIDROSIS	- (-) / Ongoing (.)	Moderate	1	Possible	-
01-718-1170 / 80/W/F	NERVOUS SYSTEM DISORDERS/ DIZZINESS/ DIZZINESS	- (-) / Ongoing (.)	Moderate	1	Possible	-
01-718-1170 / 80/W/F	NERVOUS SYSTEM DISORDERS/ SYNCOPE/ SYNCOPE	- (-) / Ongoing (.)	Severe	1	Probable	-
01-718-1170 / 80/W/F	PSYCHIATRIC DISORDERS/ AGITATION/ AGITATION	- (-) / Ongoing (.)	Severe	3	Possible	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline Low Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-718-1170 / 80/W/F	VASCULAR DISORDERS/ HYPERTENSION/ HYPERTENSION	- (-) / Ongoing (.)	Mild	1	Possible	-
01-718-1170 / 80/W/F	INVESTIGATIONS/ BODY TEMPERATURE INCREASED/ BODY TEMPERATURE INCREASED	- (-) / Ongoing (.)	Mild	1	Possible	-
01-718-1250 / 82/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-718-1250 / 82/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-
01-718-1250 / 82/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Mild	1	Probable	-
01-718-1250 / 82/W/F	NERVOUS SYSTEM DISORDERS/ BALANCE DISORDER/ BALANCE DISORDER	- (-) / Ongoing (.)	Moderate	3	Possible	-
01-718-1250 / 82/W/F	NERVOUS SYSTEM DISORDERS/ BALANCE DISORDER/ BALANCE DISORDER	- (-) / Ongoing (.)	Mild	3	Possible	-
01-718-1250 / 82/W/F	NERVOUS SYSTEM DISORDERS/ BALANCE DISORDER/ BALANCE DISORDER	- (-) / Ongoing (.)	Mild	1	Possible	-
01-718-1250 / 82/W/F	NERVOUS SYSTEM DISORDERS/ COORDINATION ABNORMAL/ COORDINATION ABNORMAL	- (-) / Ongoing (.)	Mild	1	Possible	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline Low Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day)/ Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-718-1250 / 82/W/F	INJURY, POISONING AND PROCEDURAL COMPLICATIONS/ CONTUSION/ CONTUSION	- (-)/ Ongoing (.)	Moderate	3	Remote	-
01-718-1250 / 82/W/F	INJURY, POISONING AND PROCEDURAL COMPLICATIONS/ CONTUSION/ CONTUSION	- (-)/ Ongoing (.)	Mild	3	Remote	-
01-718-1250 / 82/W/F	INJURY, POISONING AND PROCEDURAL COMPLICATIONS/ CONTUSION/ CONTUSION	- (-)/ Ongoing (.)	Mild	1	Remote	-
01-718-1250 / 82/W/F	INJURY, POISONING AND PROCEDURAL COMPLICATIONS/ FALL/ FALL	- (-)/ Ongoing (.)	Mild	1	Remote	-
01-718-1254 / 78/W/M	GASTROINTESTINAL DISORDERS/ DYSPHAGIA/ DYSPHAGIA	- (-)/ Ongoing (.)	Moderate	3		-
01-718-1254 / 78/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-)/ Ongoing (.)	Moderate	3	Probable	-
01-718-1254 / 78/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE DISCOLOURATION/ APPLICATION SITE DISCOLOURATION	- (-)/ Ongoing (.)	Moderate	3	Probable	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline Low Dose

Subject ID/ Age/Race/Se x	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-718-1254 / 78/W/M	METABOLISM AND NUTRITION DISORDERS/ FOOD CRAVING/ FOOD CRAVING	- (-) / Ongoing (.)	Moderate	3		-
01-718-1254 / 78/W/M	MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS/ ARTHRALGIA/ ARTHRALGIA	- (-) / Ongoing (.)	Moderate	3	None	-
01-718-1254 / 78/W/M	MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS/ ARTHRALGIA/ ARTHRALGIA	- (-) / Ongoing (.)	Mild	3	None	-
01-718-1254 / 78/W/M	MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS/ ARTHRALGIA/ ARTHRALGIA	- (-) / Ongoing (.)	Mild	1	None	-
01-718-1254 / 78/W/M	NERVOUS SYSTEM DISORDERS/ SOMNOLENCE/ SOMNOLENCE	- (-) / Ongoing (.)	Moderate	3	Remote	-
01-718-1254 / 78/W/M	NERVOUS SYSTEM DISORDERS/ SOMNOLENCE/ SOMNOLENCE	- (-) / Ongoing (.)	Moderate	1	Remote	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline High Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-701-1028 / 71/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE ERYTHEMA/ APPLICATION SITE ERYTHEMA	- (-) / Ongoing (.)	Mild	3	Possible	-
01-701-1028 / 71/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-
01-701-1034 / 77/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-
01-701-1034 / 77/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ FATIGUE/ FATIGUE	- (-) / Ongoing (.)	Mild	3	Possible	-
01-701-1133 / 81/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE ERYTHEMA/ APPLICATION SITE ERYTHEMA	- (-) / Ongoing (.)	Mild	3	Probable	-
01-701-1133 / 81/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE ERYTHEMA/ APPLICATION SITE ERYTHEMA	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-701-1133 / 81/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline High Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-701-1133 / 81/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-701-1146 / 75/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE ERYTHEMA/ APPLICATION SITE ERYTHEMA	- (-) / Ongoing (.)	Mild	3	Probable	-
01-701-1146 / 75/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE ERYTHEMA/ APPLICATION SITE ERYTHEMA	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-701-1146 / 75/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-
01-701-1146 / 75/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-701-1146 / 75/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE IRRITATION/ APPLICATION SITE IRRITATION	- (-) / Ongoing (.)	Mild	1	Probable	-
01-701-1146 / 75/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE IRRITATION/ APPLICATION SITE IRRITATION	- (-) / Ongoing (.)	Moderate	3	Probable	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline High Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-701-1146 / 75/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE VESICLES/ APPLICATION SITE VESICLES	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-701-1146 / 75/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ FATIGUE/ FATIGUE	- (-) / Ongoing (.)	Mild	3	Possible	-
01-701-1146 / 75/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PAIN/ APPLICATION SITE PAIN	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-701-1146 / 75/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH/ RASH	- (-) / Ongoing (.)	Mild	3	None	-
01-701-1146 / 75/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH/ RASH	- (-) / Ongoing (.)	Mild	1	None	-
01-701-1148 / 57/W/M	GASTROINTESTINAL DISORDERS/ DYSPEPSIA/ DYSPEPSIA	- (-) / Ongoing (.)	Moderate	3	None	-
01-701-1148 / 57/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE ERYTHEMA/ APPLICATION SITE ERYTHEMA	- (-) / Ongoing (.)	Mild	3	Probable	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline High Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-701-1148 / 57/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-
01-701-1148 / 57/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ACTINIC KERATOSIS/ ACTINIC KERATOSIS	- (-) / Ongoing (.)	Mild	3	None	-
01-701-1148 / 57/W/M	INFECTIONS AND INFESTATIONS / LOWER RESPIRATORY TRACT INFECTION/ LOWER RESPIRATORY TRACT INFECTION	- (-) / Ongoing (.)	Moderate	3	None	-
01-701-1148 / 57/W/M	INFECTIONS AND INFESTATIONS / LOWER RESPIRATORY TRACT INFECTION/ LOWER RESPIRATORY TRACT INFECTION	- (-) / Ongoing (.)	Moderate	1	None	-
01-701-1148 / 57/W/M	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS / EPISTAXIS/ EPISTAXIS	- (-) / Ongoing (.)	Mild	1	None	-
01-701-1148 / 57/W/M	MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS / FLANK PAIN/ FLANK PAIN	- (-) / Ongoing (.)	Moderate	1	None	-
01-701-1148 / 57/W/M	RENAL AND URINARY DISORDERS / CALCULUS URETHRAL / CALCULUS URETHRAL	- (-) / Ongoing (.)	Moderate	1	None	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline High Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-701-1148 / 57/W/M	PSYCHIATRIC DISORDERS/ DEPRESSED MOOD/ DEPRESSED MOOD	- (-) / Ongoing (.)	Moderate	3	None	-
01-701-1180 / 56/W/M	GASTROINTESTINAL DISORDERS/ VOMITING/ VOMITING	- (-) / Ongoing (.)	Mild	3	None	-
01-701-1180 / 56/W/M	GASTROINTESTINAL DISORDERS/ VOMITING/ VOMITING	- (-) / Ongoing (.)	Mild	1	None	-
01-701-1180 / 56/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE ERYTHEMA/ APPLICATION SITE ERYTHEMA	- (-) / Ongoing (.)	Moderate	3	Possible	-
01-701-1180 / 56/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Moderate	3	Possible	-
01-701-1180 / 56/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE VESICLES/ APPLICATION SITE VESICLES	- (-) / Ongoing (.)	Moderate	3	Possible	-
01-701-1180 / 56/W/M	INFECTIONS AND INFESTATIONS/ NASOPHARYNGITIS/ NASOPHARYNGITIS	- (-) / Ongoing (.)	Mild	1	None	-
01-701-1180 / 56/W/M	NERVOUS SYSTEM DISORDERS/ HEADACHE/ HEADACHE	- (-) / Ongoing (.)	Moderate	3	None	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline High Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-701-1180 / 56/W/M	RENAL AND URINARY DISORDERS/ MICTURITION URGENCY/ MICTURITION URGENCY	- (-) / Ongoing (.)	Mild	3	Possible	-
01-701-1180 / 56/W/M	RENAL AND URINARY DISORDERS/ MICTURITION URGENCY/ MICTURITION URGENCY	- (-) / Ongoing (.)	Mild	1	Possible	-
01-701-1181 / 79/W/F	PSYCHIATRIC DISORDERS/ AGITATION/ AGITATION	- (-) / Ongoing (.)	Moderate	1	None	-
01-701-1239 / 56/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE IRRITATION/ APPLICATION SITE IRRITATION	- (-) / Ongoing (.)	Mild	3	Probable	-
01-701-1239 / 56/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE IRRITATION/ APPLICATION SITE IRRITATION	- (-) / Ongoing (.)	Mild	1	Probable	-
01-701-1239 / 56/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ FATIGUE/ FATIGUE	- (-) / Ongoing (.)	Mild	3	Remote	-
01-701-1239 / 56/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Mild	3	Possible	-
01-701-1239 / 56/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Moderate	3	Possible	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline High Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-701-1239 / 56/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Mild	3	Possible	-
01-701-1239 / 56/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ SKIN ODOUR ABNORMAL/ SKIN ODOUR ABNORMAL	- (-) / Ongoing (.)	Mild	3	Remote	-
01-701-1239 / 56/W/M	INFECTIONS AND INFESTATIONS / UPPER RESPIRATORY TRACT INFECTION/ UPPER RESPIRATORY TRACT INFECTION	- (-) / Ongoing (.)	Mild	3	None	-
01-701-1239 / 56/W/M	INFECTIONS AND INFESTATIONS / UPPER RESPIRATORY TRACT INFECTION/ UPPER RESPIRATORY TRACT INFECTION	- (-) / Ongoing (.)	Mild	1	None	-
01-701-1239 / 56/W/M	INFECTIONS AND INFESTATIONS / HORDEOLUM / HORDEOLUM	- (-) / Ongoing (.)	Mild	3	None	-
01-701-1275 / 61/A/M	GASTROINTESTINAL DISORDERS / NAUSEA / NAUSEA	- (-) / Ongoing (.)	Mild	3	Possible	-
01-701-1275 / 61/A/M	GASTROINTESTINAL DISORDERS / NAUSEA / NAUSEA	- (-) / Ongoing (.)	Mild	1	Possible	-
01-701-1275 / 61/A/M	GASTROINTESTINAL DISORDERS / VOMITING / VOMITING	- (-) / Ongoing (.)	Mild	1	Possible	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline High Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-701-1275 / 61/A/M	GASTROINTESTINAL DISORDERS/ SALIVARY HYPERSECRETION/ SALIVARY HYPERSECRETION	- (-) / Ongoing (.)	Mild	3	Possible	-
01-701-1275 / 61/A/M	GASTROINTESTINAL DISORDERS/ SALIVARY HYPERSECRETION/ SALIVARY HYPERSECRETION	- (-) / Ongoing (.)	Mild	1	Possible	-
01-701-1275 / 61/A/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Mild	3	Possible	-
01-701-1275 / 61/A/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Mild	1	Possible	-
01-701-1275 / 61/A/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Mild	3	Possible	-
01-701-1275 / 61/A/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Mild	1	Possible	-
01-701-1275 / 61/A/M	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS/ COUGH/ COUGH	- (-) / Ongoing (.)	Mild	3	None	-
01-701-1275 / 61/A/M	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS/ COUGH/ COUGH	- (-) / Ongoing (.)	Mild	1	None	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline High Dose

Subject ID/ Age/Race/Se x	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-701-1275 / 61/A/M	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS/ NASAL CONGESTION/ NASAL CONGESTION	- (-) / Ongoing (.)	Mild	3	None	-
01-701-1275 / 61/A/M	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS/ NASAL CONGESTION/ NASAL CONGESTION	- (-) / Ongoing (.)	Mild	1	None	-
01-701-1275 / 61/A/M	NERVOUS SYSTEM DISORDERS/ PAROSMIA/ PAROSMIA	- (-) / Ongoing (.)	Mild	3	Possible	-
01-701-1275 / 61/A/M	NERVOUS SYSTEM DISORDERS/ PAROSMIA/ PAROSMIA	- (-) / Ongoing (.)	Mild	1	Possible	-
01-701-1287 / 56/W/F	GASTROINTESTINAL DISORDERS/ SALIVARY HYPERSECRETION/ SALIVARY HYPERSECRETION	- (-) / Ongoing (.)	Mild	3	None	-
01-701-1287 / 56/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE ERYTHEMA/ APPLICATION SITE ERYTHEMA	- (-) / Ongoing (.)	Mild	3	Probable	-
01-701-1287 / 56/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Mild	3	Possible	-
01-701-1287 / 56/W/F	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS/ RHINORRHOEA/ RHINORRHOEA	- (-) / Ongoing (.)	Mild	3	None	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline High Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-701-1287 / 56/W/F	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS/ RHINORRHOEA/ RHINORRHOEA	- (-) / Ongoing (.)	Mild	1	None	-
01-701-1302 / 61/W/M	GASTROINTESTINAL DISORDERS/ STOMACH DISCOMFORT/ STOMACH DISCOMFORT	- (-) / Ongoing (.)	Mild	3	Possible	-
01-701-1302 / 61/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE ERYTHEMA/ APPLICATION SITE ERYTHEMA	- (-) / Ongoing (.)	Mild	3	Probable	-
01-701-1302 / 61/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-
01-701-1302 / 61/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ MALAISE/ MALAISE	- (-) / Ongoing (.)	Mild	3	Remote	-
01-701-1302 / 61/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ MALAISE/ MALAISE	- (-) / Ongoing (.)	Moderate	3	Remote	-
01-701-1302 / 61/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ PAIN/ PAIN	- (-) / Ongoing (.)	Mild	3	Possible	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline High Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-701-1302 / 61/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PERSPIRATION/ APPLICATION SITE PERSPIRATION	- (-) / Ongoing (.)	Mild	3	Possible	-
01-701-1302 / 61/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ FEELING ABNORMAL/ FEELING ABNORMAL	- (-) / Ongoing (.)	Mild	3	Possible	-
01-701-1302 / 61/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ HYPERHIDROSIS/ HYPERHIDROSIS	- (-) / Ongoing (.)	Mild	3	Possible	-
01-701-1302 / 61/W/M	INFECTIONS AND INFESTATIONS/ RHINITIS/ RHINITIS	- (-) / Ongoing (.)	Mild	3	None	-
01-701-1302 / 61/W/M	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS/ NASAL CONGESTION/ NASAL CONGESTION	- (-) / Ongoing (.)	Mild	3	None	-
01-701-1302 / 61/W/M	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS/ PHARYNGOLARYNGEAL PAIN/ PHARYNGOLARYNGEAL PAIN	- (-) / Ongoing (.)	Mild	3	None	-
01-701-1302 / 61/W/M	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS/ EPISTAXIS/ EPISTAXIS	- (-) / Ongoing (.)	Mild	3	Remote	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline High Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-701-1302 / 61/W/M	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS/ PRODUCTIVE COUGH/ PRODUCTIVE COUGH	- (-) / Ongoing (.)	Mild	3	None	-
01-701-1302 / 61/W/M	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS/ RESPIRATORY TRACT CONGESTION/ RESPIRATORY TRACT CONGESTION	- (-) / Ongoing (.)	Mild	3	None	-
01-701-1302 / 61/W/M	MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS/ MYALGIA/ MYALGIA	- (-) / Ongoing (.)	Mild	3	Possible	-
01-701-1302 / 61/W/M	NERVOUS SYSTEM DISORDERS/ HEADACHE/ HEADACHE	- (-) / Ongoing (.)	Mild	3	None	-
01-701-1302 / 61/W/M	NERVOUS SYSTEM DISORDERS/ DIZZINESS/ DIZZINESS	- (-) / Ongoing (.)	Moderate	1	Remote	-
01-701-1302 / 61/W/M	NERVOUS SYSTEM DISORDERS/ DIZZINESS/ DIZZINESS	- (-) / Ongoing (.)	Mild	3	Possible	-
01-701-1302 / 61/W/M	PSYCHIATRIC DISORDERS/ LIBIDO DECREASED/ LIBIDO DECREASED	- (-) / Ongoing (.)	Mild	3	Possible	-
01-701-1302 / 61/W/M	PSYCHIATRIC DISORDERS/ LISTLESS/ LISTLESS	- (-) / Ongoing (.)	Mild	3	Possible	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline High Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-701-1302 / 61/W/M	INJURY, POISONING AND PROCEDURAL COMPLICATIONS/ CONTUSION/ CONTUSION	- (-) / Ongoing (.)	Mild	3	Remote	-
01-701-1302 / 61/W/M	INJURY, POISONING AND PROCEDURAL COMPLICATIONS/ CONTUSION/ CONTUSION	- (-) / Ongoing (.)	Mild	1	Remote	-
01-701-1360 / 67/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE ERYTHEMA/ APPLICATION SITE ERYTHEMA	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-701-1360 / 67/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-701-1360 / 67/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE VESICLES/ APPLICATION SITE VESICLES	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-701-1383 / 72/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE ERYTHEMA/ APPLICATION SITE ERYTHEMA	- (-) / Ongoing (.)	Mild	1	Possible	-
01-701-1383 / 72/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE ERYTHEMA/ APPLICATION SITE ERYTHEMA	- (-) / Ongoing (.)	Mild	3	Possible	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline High Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-701-1383 / 72/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Mild	1	Probable	-
01-701-1383 / 72/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Mild	3	Possible	-
01-701-1383 / 72/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Moderate	3	Possible	-
01-701-1383 / 72/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE IRRITATION/ APPLICATION SITE IRRITATION	- (-) / Ongoing (.)	Mild	3	Possible	-
01-701-1383 / 72/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE IRRITATION/ APPLICATION SITE IRRITATION	- (-) / Ongoing (.)	Moderate	3	Possible	-
01-701-1383 / 72/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE VESICLES/ APPLICATION SITE VESICLES	- (-) / Ongoing (.)	Mild	1	Possible	-
01-701-1383 / 72/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PAIN/ APPLICATION SITE PAIN	- (-) / Ongoing (.)	Mild	1	Probable	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline High Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-701-1383 / 72/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ CHEST DISCOMFORT/ CHEST DISCOMFORT	- (-) / Ongoing (.)	Mild	1	None	-
01-701-1383 / 72/W/F	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS/ COUGH/ COUGH	- (-) / Ongoing (.)	Moderate	1	None	-
01-701-1383 / 72/W/F	NERVOUS SYSTEM DISORDERS/ HEADACHE/ HEADACHE	- (-) / Ongoing (.)	Mild	1	None	-
01-701-1444 / 63/W/M	GASTROINTESTINAL DISORDERS/ SALIVARY HYPERSECRETION/ SALIVARY HYPERSECRETION	- (-) / Ongoing (.)	Mild	3	Possible	-
01-701-1444 / 63/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE ERYTHEMA/ APPLICATION SITE ERYTHEMA	- (-) / Ongoing (.)	Mild	3	Possible	-
01-701-1444 / 63/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE ERYTHEMA/ APPLICATION SITE ERYTHEMA	- (-) / Ongoing (.)	Moderate	3	Possible	-
01-701-1444 / 63/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-
01-701-1444 / 63/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Moderate	3	Probable	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline High Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-701-1444 / 63/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE IRRITATION/ APPLICATION SITE IRRITATION	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-701-1444 / 63/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE VESICLES/ APPLICATION SITE VESICLES	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-701-1444 / 63/W/M	NERVOUS SYSTEM DISORDERS/ PARAESTHESIA/ PARAESTHESIA	- (-) / Ongoing (.)	Mild	1	None	-
01-703-1076 / 69/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-
01-703-1076 / 69/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-703-1076 / 69/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE DERMATITIS/ APPLICATION SITE DERMATITIS	- (-) / Ongoing (.)	Mild	3	Probable	-
01-703-1076 / 69/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ HYPERHIDROSIS/ HYPERHIDROSIS	- (-) / Ongoing (.)	Mild	3	Possible	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline High Dose

Subject ID/ Age/Race/Se x	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-703-1076 / 69/W/M	METABOLISM AND NUTRITION DISORDERS/ HYPERCHOLESTEROLAEMIA/ HYPERCHOLESTEROLAEMIA	- (-) / Ongoing (.)	Moderate	3	None	-
01-703-1076 / 69/W/M	INVESTIGATIONS/ BIOPSY PROSTATE/ BIOPSY PROSTATE	- (-) / Ongoing (.)	Moderate	1	None	-
01-703-1076 / 69/W/M	REPRODUCTIVE SYSTEM AND BREAST DISORDERS/ BENIGN PROSTATIC HYPERPLASIA/ BENIGN PROSTATIC HYPERPLASIA	- (-) / Ongoing (.)	Moderate	3	None	-
01-703-1258 / 78/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE DERMATITIS/ APPLICATION SITE DERMATITIS	- (-) / Ongoing (.)	Mild	3	Probable	-
01-703-1258 / 78/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE DERMATITIS/ APPLICATION SITE DERMATITIS	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-703-1258 / 78/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE DERMATITIS/ APPLICATION SITE DERMATITIS	- (-) / Ongoing (.)	Mild	1	Probable	-
01-703-1258 / 78/W/F	INFECTIONS AND INFESTATIONS/ UPPER RESPIRATORY TRACT INFECTION/ UPPER RESPIRATORY TRACT INFECTION	- (-) / Ongoing (.)	Mild	3	None	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline High Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-703-1258 / 78/W/F	INFECTIONS AND INFESTATIONS/ UPPER RESPIRATORY TRACT INFECTION/ UPPER RESPIRATORY TRACT INFECTION	- (-) / Ongoing (.)	Mild	1	None	-
01-703-1258 / 78/W/F	NERVOUS SYSTEM DISORDERS/ DIZZINESS/ DIZZINESS	- (-) / Ongoing (.)	Moderate	3	None	-
01-703-1258 / 78/W/F	NERVOUS SYSTEM DISORDERS/ DIZZINESS/ DIZZINESS	- (-) / Ongoing (.)	Mild	3	None	-
01-703-1295 / 88/W/F	MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS/ ARTHRITIS/ ARTHRITIS	- (-) / Ongoing (.)	Moderate	3	None	-
01-703-1335 / 67/B/F	CARDIAC DISORDERS/ ATRIOVENTRICULAR BLOCK SECOND DEGREE/ ATRIOVENTRICULAR BLOCK SECOND DEGREE	- (-) / Ongoing (.)	Mild	3	None	-
01-703-1335 / 67/B/F	CARDIAC DISORDERS/ ATRIOVENTRICULAR BLOCK SECOND DEGREE/ ATRIOVENTRICULAR BLOCK SECOND DEGREE	- (-) / Ongoing (.)	Mild	1	None	-
01-703-1403 / 67/W/M	GASTROINTESTINAL DISORDERS/ DIARRHOEA/ DIARRHOEA	- (-) / Ongoing (.)	Moderate	1	Probable	-
01-703-1403 / 67/W/M	GASTROINTESTINAL DISORDERS/ VOMITING/ VOMITING	- (-) / Ongoing (.)	Moderate	1	Probable	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline High Dose

Subject ID/ Age/Race/Se x	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-703-1403 / 67/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ CHEST DISCOMFORT/ CHEST DISCOMFORT	- (-) / Ongoing (.)	Mild	1	Probable	-
01-703-1403 / 67/W/M	INVESTIGATIONS/ WEIGHT DECREASED/ WEIGHT DECREASED	- (-) / Ongoing (.)	Moderate	3	None	-
01-703-1403 / 67/W/M	INVESTIGATIONS/ WEIGHT DECREASED/ WEIGHT DECREASED	- (-) / Ongoing (.)	Moderate	1	None	-
01-703-1439 / 76/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE IRRITATION/ APPLICATION SITE IRRITATION	- (-) / Ongoing (.)	Mild	3	Probable	-
01-703-1439 / 76/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE IRRITATION/ APPLICATION SITE IRRITATION	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-704-1008 / 76/W/F	CARDIAC DISORDERS/ SINUS BRADYCARDIA/ SINUS BRADYCARDIA	- (-) / Ongoing (.)	Moderate	3	None	-
01-704-1008 / 76/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ HYPERHIDROSIS/ HYPERHIDROSIS	- (-) / Ongoing (.)	Mild	3	Possible	-
01-704-1008 / 76/W/F	NERVOUS SYSTEM DISORDERS/ TRANSIENT ISCHAEMIC ATTACK/ TRANSIENT ISCHAEMIC ATTACK	- (-) / Ongoing (.)	Severe	1	None	-

Copyright © DH

**Adverse Events
Safety Analysis Set**

Xanomeline High Dose

Subject ID/ Age/Race/Se x	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-704-1017 / 77/W/M	CARDIAC DISORDERS/ MYOCARDIAL INFARCTION/ MYOCARDIAL INFARCTION	- (-) / Ongoing (.)	Mild	3	None	-
01-704-1017 / 77/W/M	CARDIAC DISORDERS/ CARDIAC DISORDER/ CARDIAC DISORDER	- (-) / Ongoing (.)	Mild	3	None	-
01-704-1017 / 77/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-
01-704-1017 / 77/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Mild	1	Probable	-
01-704-1017 / 77/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH/ RASH	- (-) / Ongoing (.)	Mild	3	Probable	-
01-704-1017 / 77/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH/ RASH	- (-) / Ongoing (.)	Mild	1	Probable	-
01-704-1017 / 77/W/M	INFECTIONS AND INFESTATIONS/ INFLUENZA/ INFLUENZA	- (-) / Ongoing (.)	Mild	1	None	-
01-704-1017 / 77/W/M	CONGENITAL, FAMILIAL AND GENETIC DISORDERS/ VENTRICULAR SEPTAL DEFECT/ VENTRICULAR SEPTAL DEFECT	- (-) / Ongoing (.)	Mild	3	None	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline High Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-704-1065 / 75/W/M	GASTROINTESTINAL DISORDERS/ DIARRHOEA/ DIARRHOEA	- (-) / Ongoing (.)	Mild	1	Remote	-
01-704-1065 / 75/W/M	GASTROINTESTINAL DISORDERS/ ABDOMINAL DISCOMFORT/ ABDOMINAL DISCOMFORT	- (-) / Ongoing (.)	Mild	3	Remote	-
01-704-1065 / 75/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-704-1065 / 75/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE IRRITATION/ APPLICATION SITE IRRITATION	- (-) / Ongoing (.)	Mild	3	Probable	-
01-704-1065 / 75/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ CHILLS/ CHILLS	- (-) / Ongoing (.)	Mild	1	Remote	-
01-704-1065 / 75/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ MALAISE/ MALAISE	- (-) / Ongoing (.)	Mild	3	Possible	-
01-704-1065 / 75/W/M	CARDIAC DISORDERS/ SINUS BRADYCARDIA/ SINUS BRADYCARDIA	- (-) / Ongoing (.)	Mild	3	None	-

Copyright © DH

**Adverse Events
Safety Analysis Set**

Xanomeline High Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-704-1065 / 75/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ HYPERHIDROSIS/ HYPERHIDROSIS	- (-) / Ongoing (.)	Mild	3	Possible	-
01-704-1065 / 75/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH/ RASH	- (-) / Ongoing (.)	Mild	3	Probable	-
01-704-1065 / 75/W/M	NERVOUS SYSTEM DISORDERS/ DIZZINESS/ DIZZINESS	- (-) / Ongoing (.)	Mild	1	Remote	-
01-704-1074 / 80/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Mild	3	Probable	-
01-704-1074 / 80/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-
01-704-1093 / 79/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-
01-704-1093 / 79/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH/ RASH	- (-) / Ongoing (.)	Mild	3	Probable	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline High Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-704-1093 / 79/W/M	INVESTIGATIONS/ BLOOD GLUCOSE INCREASED/ BLOOD GLUCOSE INCREASED	- (-) / Ongoing (.)	Mild	3	None	-
01-704-1093 / 79/W/M	INVESTIGATIONS/ BLOOD GLUCOSE INCREASED/ BLOOD GLUCOSE INCREASED	- (-) / Ongoing (.)	Mild	1	None	-
01-704-1241 / 86/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH/ RASH	- (-) / Ongoing (.)	Moderate	3	None	-
01-704-1241 / 86/W/M	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS/ DYSпноEA/ DYSпноEA	- (-) / Ongoing (.)	Mild	3	None	-
01-704-1266 / 82/W/M	CARDIAC DISORDERS/ ATRIAL FIBRILLATION/ ATRIAL FIBRILLATION	- (-) / Ongoing (.)	Mild	3	None	-
01-704-1266 / 82/W/M	CARDIAC DISORDERS/ ATRIAL FIBRILLATION/ ATRIAL FIBRILLATION	- (-) / Ongoing (.)	Mild	1	None	-
01-704-1266 / 82/W/M	CARDIAC DISORDERS/ ATRIAL FLUTTER/ ATRIAL FLUTTER	- (-) / Ongoing (.)	Mild	3	None	-
01-704-1266 / 82/W/M	CARDIAC DISORDERS/ ATRIAL FLUTTER/ ATRIAL FLUTTER	- (-) / Ongoing (.)	Mild	1	None	-
01-704-1266 / 82/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Mild	3	Probable	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline High Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-704-1266 / 82/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-704-1266 / 82/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Mild	3	Probable	-
01-704-1266 / 82/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Moderate	1	Probable	-
01-704-1266 / 82/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Mild	1	Probable	-
01-704-1266 / 82/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-
01-704-1266 / 82/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Mild	1	Probable	-
01-704-1266 / 82/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ HYPERHIDROSIS/ HYPERHIDROSIS	- (-) / Ongoing (.)	Mild	3	Possible	-
01-704-1266 / 82/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ HYPERHIDROSIS/ HYPERHIDROSIS	- (-) / Ongoing (.)	Mild	1	Possible	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline High Dose

Subject ID/ Age/Race/Se x	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-704-1266 / 82/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ BLISTER/ BLISTER	- (-) / Ongoing (.)	Mild	3	Probable	-
01-704-1266 / 82/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ BLISTER/ BLISTER	- (-) / Ongoing (.)	Mild	1	Probable	-
01-704-1266 / 82/W/M	IMMUNE SYSTEM DISORDERS/ SEASONAL ALLERGY/ SEASONAL ALLERGY	- (-) / Ongoing (.)	Mild	3	None	-
01-704-1332 / 80/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-
01-704-1332 / 80/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Mild	1	Probable	-
01-704-1332 / 80/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH/ RASH	- (-) / Ongoing (.)	Mild	3	None	-
01-704-1332 / 80/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH/ RASH	- (-) / Ongoing (.)	Moderate	3	None	-
01-704-1332 / 80/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH/ RASH	- (-) / Ongoing (.)	Moderate	1	None	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline High Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-704-1332 / 80/W/M	NERVOUS SYSTEM DISORDERS/ BURNING SENSATION/ BURNING SENSATION	- (-) / Ongoing (.)	Mild	3	Probable	-
01-705-1280 / 56/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Mild	3	Possible	-
01-705-1281 / 73/B/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Mild	3	Possible	-
01-705-1281 / 73/B/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Moderate	3	Possible	-
01-705-1281 / 73/B/F	INJURY, POISONING AND PROCEDURAL COMPLICATIONS/ EXCORIATION/ EXCORIATION	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-705-1303 / 72/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Mild	3	Possible	-
01-705-1303 / 72/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Mild	1	Possible	-
01-705-1303 / 72/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH/ RASH	- (-) / Ongoing (.)	Mild	3	Possible	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline High Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-705-1303 / 72/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH/ RASH	- (-) / Ongoing (.)	Moderate	1	Possible	-
01-705-1310 / 74/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH PRURITIC/ RASH PRURITIC	- (-) / Ongoing (.)	Moderate	3	Possible	-
01-705-1310 / 74/W/F	VASCULAR DISORDERS/ WOUND HAEMORRHAGE/ WOUND HAEMORRHAGE	- (-) / Ongoing (.)	Moderate	3	Possible	-
01-706-1049 / 60/W/F	NERVOUS SYSTEM DISORDERS/ SYNCOPE/ SYNCOPE	- (-) / Ongoing (.)	Moderate	1	Possible	-
01-706-1049 / 60/W/F	NERVOUS SYSTEM DISORDERS/ SYNCOPE/ SYNCOPE	- (-) / Ongoing (.)	Severe	1	Probable	-
01-708-1178 / 77/B/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-
01-708-1178 / 77/B/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Mild	1	Probable	-
01-708-1178 / 77/B/F	CARDIAC DISORDERS/ ATRIAL FIBRILLATION/ ATRIAL FIBRILLATION	- (-) / Ongoing (.)	Severe	1	Possible	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline High Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-708-1178 / 77/B/F	INFECTIONS AND INFESTATIONS/ CYSTITIS/ CYSTITIS	- (-) / Ongoing (.)	Mild	1	Remote	-
01-708-1178 / 77/B/F	INFECTIONS AND INFESTATIONS/ NASOPHARYNGITIS/ NASOPHARYNGITIS	- (-) / Ongoing (.)	Mild	1	None	-
01-708-1178 / 77/B/F	MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS/ FLANK PAIN/ FLANK PAIN	- (-) / Ongoing (.)	Mild	3	None	-
01-708-1178 / 77/B/F	NERVOUS SYSTEM DISORDERS/ DIZZINESS/ DIZZINESS	- (-) / Ongoing (.)	Severe	1	Possible	-
01-708-1178 / 77/B/F	CONGENITAL, FAMILIAL AND GENETIC DISORDERS/ VENTRICULAR SEPTAL DEFECT/ VENTRICULAR SEPTAL DEFECT	- (-) / Ongoing (.)	Mild	3	None	-
01-708-1178 / 77/B/F	SOCIAL CIRCUMSTANCES/ ALCOHOL USE/ ALCOHOL USE	- (-) / Ongoing (.)	Mild	1	None	-
01-708-1213 / 76/W/F	CARDIAC DISORDERS/ ATRIAL FIBRILLATION/ ATRIAL FIBRILLATION	- (-) / Ongoing (.)	Mild	3	Possible	-
01-708-1213 / 76/W/F	CARDIAC DISORDERS/ ATRIAL FIBRILLATION/ ATRIAL FIBRILLATION	- (-) / Ongoing (.)	Mild	1	Possible	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline High Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-708-1216 / 78/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE ERYTHEMA/ APPLICATION SITE ERYTHEMA	- (-) / Ongoing (.)	Mild	3	Probable	-
01-708-1216 / 78/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE ERYTHEMA/ APPLICATION SITE ERYTHEMA	- (-) / Ongoing (.)	Mild	1	Probable	-
01-708-1216 / 78/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-
01-708-1216 / 78/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE SWELLING/ APPLICATION SITE SWELLING	- (-) / Ongoing (.)	Mild	3	Probable	-
01-708-1336 / 73/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE ERYTHEMA/ APPLICATION SITE ERYTHEMA	- (-) / Ongoing (.)	Mild	3	Probable	-
01-708-1336 / 73/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE ERYTHEMA/ APPLICATION SITE ERYTHEMA	- (-) / Ongoing (.)	Mild	1	Probable	-
01-708-1336 / 73/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Mild	1	Probable	-
01-708-1336 / 73/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline High Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-708-1336 / 73/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Mild	1	Probable	-
01-708-1336 / 73/W/M	NERVOUS SYSTEM DISORDERS/ DIZZINESS/ DIZZINESS	- (-) / Ongoing (.)	Mild	1	Possible	-
01-708-1336 / 73/W/M	NERVOUS SYSTEM DISORDERS/ DIZZINESS/ DIZZINESS	- (-) / Ongoing (.)	Mild	1	Possible	-
01-708-1347 / 61/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE ERYTHEMA/ APPLICATION SITE ERYTHEMA	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-708-1347 / 61/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE ERYTHEMA/ APPLICATION SITE ERYTHEMA	- (-) / Ongoing (.)	Moderate	1	Probable	-
01-708-1347 / 61/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE SWELLING/ APPLICATION SITE SWELLING	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-708-1347 / 61/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE SWELLING/ APPLICATION SITE SWELLING	- (-) / Ongoing (.)	Moderate	1	Probable	-
01-708-1347 / 61/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Moderate	3	Probable	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline High Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-708-1347 / 61/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Moderate	1	Probable	-
01-708-1347 / 61/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-
01-708-1347 / 61/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Mild	1	Probable	-
01-708-1372 / 84/W/M	CARDIAC DISORDERS/ ATRIOVENTRICULAR BLOCK SECOND DEGREE/ ATRIOVENTRICULAR BLOCK SECOND DEGREE	- (-) / Ongoing (.)	Moderate	3	None	-
01-708-1406 / 71/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ OEDEMA PERIPHERAL/ OEDEMA PERIPHERAL	- (-) / Ongoing (.)	Mild	3	None	-
01-708-1406 / 71/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ OEDEMA PERIPHERAL/ OEDEMA PERIPHERAL	- (-) / Ongoing (.)	Mild	3	None	-
01-709-1029 / 82/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE ERYTHEMA/ APPLICATION SITE ERYTHEMA	- (-) / Ongoing (.)	Mild	3	Probable	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline High Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-709-1029 / 82/W/M	CARDIAC DISORDERS/ MYOCARDIAL INFARCTION/ MYOCARDIAL INFARCTION	- (-) / Ongoing (.)	Mild	3	None	-
01-709-1029 / 82/W/M	CARDIAC DISORDERS/ MYOCARDIAL INFARCTION/ MYOCARDIAL INFARCTION	- (-) / Ongoing (.)	Mild	1	None	-
01-709-1029 / 82/W/M	CARDIAC DISORDERS/ MYOCARDIAL INFARCTION/ MYOCARDIAL INFARCTION	- (-) / Ongoing (.)	Mild	3	None	-
01-709-1029 / 82/W/M	CARDIAC DISORDERS/ MYOCARDIAL INFARCTION/ MYOCARDIAL INFARCTION	- (-) / Ongoing (.)	Mild	1	None	-
01-709-1029 / 82/W/M	CARDIAC DISORDERS/ MYOCARDIAL INFARCTION/ MYOCARDIAL INFARCTION	- (-) / Ongoing (.)	Mild	3	Remote	-
01-709-1029 / 82/W/M	CARDIAC DISORDERS/ SINUS BRADYCARDIA/ SINUS BRADYCARDIA	- (-) / Ongoing (.)	Mild	3	Remote	-
01-709-1029 / 82/W/M	CARDIAC DISORDERS/ SINUS BRADYCARDIA/ SINUS BRADYCARDIA	- (-) / Ongoing (.)	Mild	1	Remote	-
01-709-1029 / 82/W/M	CARDIAC DISORDERS/ SINUS BRADYCARDIA/ SINUS BRADYCARDIA	- (-) / Ongoing (.)	Mild	3	Remote	-
01-709-1029 / 82/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-
01-709-1029 / 82/W/M	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS/ COUGH/ COUGH	- (-) / Ongoing (.)	Mild	3	None	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline High Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-709-1029 / 82/W/M	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS/ COUGH/ COUGH	- (-) / Ongoing (.)	Mild	1	None	-
01-709-1029 / 82/W/M	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS/ PHARYNGEAL ERYTHEMA/ PHARYNGEAL ERYTHEMA	- (-) / Ongoing (.)	Mild	3	None	-
01-709-1029 / 82/W/M	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS/ PHARYNGEAL ERYTHEMA/ PHARYNGEAL ERYTHEMA	- (-) / Ongoing (.)	Mild	1	None	-
01-709-1029 / 82/W/M	MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS/ MUSCLE SPASMS/ MUSCLE SPASMS	- (-) / Ongoing (.)	Mild	3	Remote	-
01-709-1029 / 82/W/M	MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS/ MUSCLE SPASMS/ MUSCLE SPASMS	- (-) / Ongoing (.)	Mild	1	Remote	-
01-709-1099 / 79/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-
01-709-1099 / 79/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-709-1099 / 79/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE VESICLES/ APPLICATION SITE VESICLES	- (-) / Ongoing (.)	Mild	3	Probable	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline High Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-709-1099 / 79/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE DERMATITIS/ APPLICATION SITE DERMATITIS	- (-) / Ongoing (.)	Mild	3	Probable	-
01-709-1099 / 79/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE DERMATITIS/ APPLICATION SITE DERMATITIS	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-709-1099 / 79/W/F	INFECTIONS AND INFESTATIONS/ NASOPHARYNGITIS/ NASOPHARYNGITIS	- (-) / Ongoing (.)	Mild	3	None	-
01-709-1099 / 79/W/F	INFECTIONS AND INFESTATIONS/ NASOPHARYNGITIS/ NASOPHARYNGITIS	- (-) / Ongoing (.)	Mild	1	None	-
01-709-1099 / 79/W/F	SURGICAL AND MEDICAL PROCEDURES/ ACROCHORDON EXCISION/ ACROCHORDON EXCISION	- (-) / Ongoing (.)	Mild	1	None	-
01-709-1168 / 72/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-709-1168 / 72/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Moderate	1	Probable	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline High Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-709-1168 / 72/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH/ RASH	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-709-1168 / 72/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH/ RASH	- (-) / Ongoing (.)	Moderate	1	Probable	-
01-709-1168 / 72/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ SKIN IRRITATION/ SKIN IRRITATION	- (-) / Ongoing (.)	Mild	3	Probable	-
01-709-1168 / 72/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ SKIN IRRITATION/ SKIN IRRITATION	- (-) / Ongoing (.)	Mild	1	Probable	-
01-709-1238 / 69/W/M	GASTROINTESTINAL DISORDERS/ DIARRHOEA/ DIARRHOEA	- (-) / Ongoing (.)	Moderate	1	None	-
01-709-1238 / 69/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-709-1238 / 69/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE DERMATITIS/ APPLICATION SITE DERMATITIS	- (-) / Ongoing (.)	Moderate	3	Probable	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline High Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-709-1238 / 69/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE DISCHARGE/ APPLICATION SITE DISCHARGE	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-709-1238 / 69/W/M	INFECTIONS AND INFESTATIONS/ UPPER RESPIRATORY TRACT INFECTION/ UPPER RESPIRATORY TRACT INFECTION	- (-) / Ongoing (.)	Moderate	3	None	-
01-709-1238 / 69/W/M	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS/ COUGH/ COUGH	- (-) / Ongoing (.)	Moderate	3	None	-
01-709-1238 / 69/W/M	SURGICAL AND MEDICAL PROCEDURES/ SKIN LESION EXCISION/ SKIN LESION EXCISION	- (-) / Ongoing (.)	Mild	1	None	-
01-709-1238 / 69/W/M	INJURY, POISONING AND PROCEDURAL COMPLICATIONS/ HIP FRACTURE/ HIP FRACTURE	- (-) / Ongoing (.)	Moderate	1	None	-
01-709-1309 / 65/W/M	GASTROINTESTINAL DISORDERS/ VOMITING/ VOMITING	- (-) / Ongoing (.)	Mild	3	Possible	-
01-709-1309 / 65/W/M	GASTROINTESTINAL DISORDERS/ VOMITING/ VOMITING	- (-) / Ongoing (.)	Mild	1	Possible	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline High Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-709-1309 / 65/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-
01-709-1309 / 65/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ FEELING COLD/ FEELING COLD	- (-) / Ongoing (.)	Mild	3	None	-
01-709-1309 / 65/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH MACULO-PAPULAR/ RASH MACULO-PAPULAR	- (-) / Ongoing (.)	Mild	3	Possible	-
01-709-1309 / 65/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH MACULO-PAPULAR/ RASH MACULO-PAPULAR	- (-) / Ongoing (.)	Mild	3	Probable	-
01-709-1309 / 65/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH MACULO-PAPULAR/ RASH MACULO-PAPULAR	- (-) / Ongoing (.)	Mild	1	Possible	-
01-709-1309 / 65/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH PAPULAR/ RASH PAPULAR	- (-) / Ongoing (.)	Mild	3	Possible	-
01-709-1309 / 65/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH PAPULAR/ RASH PAPULAR	- (-) / Ongoing (.)	Mild	1	Possible	-
01-709-1309 / 65/W/M	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS/ NASAL CONGESTION/ NASAL CONGESTION	- (-) / Ongoing (.)	Mild	1	Remote	-

Copyright © DH

**Adverse Events
Safety Analysis Set**

Xanomeline High Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-709-1309 / 65/W/M	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS/ ALLERGIC GRANULOMATOUS ANGIITIS/ ALLERGIC GRANULOMATOUS ANGIITIS	- (-) / Ongoing (.)	Mild	1	None	-
01-709-1309 / 65/W/M	NERVOUS SYSTEM DISORDERS/ DIZZINESS/ DIZZINESS	- (-) / Ongoing (.)	Mild	3	None	-
01-709-1309 / 65/W/M	NERVOUS SYSTEM DISORDERS/ DIZZINESS/ DIZZINESS	- (-) / Ongoing (.)	Mild	1	None	-
01-709-1309 / 65/W/M	PSYCHIATRIC DISORDERS/ NIGHTMARE/ NIGHTMARE	- (-) / Ongoing (.)	Mild	1	Remote	-
01-709-1309 / 65/W/M	INVESTIGATIONS/ BIOPSY/ BIOPSY	- (-) / Ongoing (.)	Mild	1	None	-
01-709-1329 / 70/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ PYREXIA/ PYREXIA	- (-) / Ongoing (.)	Mild	1	Remote	-
01-709-1329 / 70/W/M	NERVOUS SYSTEM DISORDERS/ DIZZINESS/ DIZZINESS	- (-) / Ongoing (.)	Mild	1	Possible	-
01-709-1424 / 77/W/M	NERVOUS SYSTEM DISORDERS/ SYNCOPE/ SYNCOPE	- (-) / Ongoing (.)	Moderate	1	Possible	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline High Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-710-1006 / 77/W/M	GASTROINTESTINAL DISORDERS/ SALIVARY HYPERSECRETION/ SALIVARY HYPERSECRETION	- (-) / Ongoing (.)	Mild	3	Possible	-
01-710-1006 / 77/W/M	CARDIAC DISORDERS/ SINUS BRADYCARDIA/ SINUS BRADYCARDIA	- (-) / Ongoing (.)	Moderate	3	Remote	-
01-710-1006 / 77/W/M	CARDIAC DISORDERS/ SINUS BRADYCARDIA/ SINUS BRADYCARDIA	- (-) / Ongoing (.)	Moderate	1	Remote	-
01-710-1006 / 77/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Moderate	3	Possible	-
01-710-1006 / 77/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ SKIN IRRITATION/ SKIN IRRITATION	- (-) / Ongoing (.)	Mild	3	Possible	-
01-710-1006 / 77/W/M	INFECTIONS AND INFESTATIONS/ URINARY TRACT INFECTION/ URINARY TRACT INFECTION	- (-) / Ongoing (.)	Mild	1	None	-
01-710-1006 / 77/W/M	NERVOUS SYSTEM DISORDERS/ DIZZINESS/ DIZZINESS	- (-) / Ongoing (.)	Mild	1	None	-
01-710-1006 / 77/W/M	NERVOUS SYSTEM DISORDERS/ DIZZINESS/ DIZZINESS	- (-) / Ongoing (.)	Mild	1	None	-
01-710-1006 / 77/W/M	RENAL AND URINARY DISORDERS/ NEPHROLITHIASIS/ NEPHROLITHIASIS	- (-) / Ongoing (.)	Moderate	1	None	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline High Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-710-1006 / 77/W/M	INJURY, POISONING AND PROCEDURAL COMPLICATIONS/ CONTUSION/ CONTUSION	- (-) / Ongoing (.)	Mild	3	None	-
01-710-1006 / 77/W/M	INJURY, POISONING AND PROCEDURAL COMPLICATIONS/ FALL/ FALL	- (-) / Ongoing (.)	Mild	1	None	-
01-710-1006 / 77/W/M	INJURY, POISONING AND PROCEDURAL COMPLICATIONS/ FACIAL BONES FRACTURE/ FACIAL BONES FRACTURE	- (-) / Ongoing (.)	Moderate	3	None	-
01-710-1021 / 79/B/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ CHEST PAIN/ CHEST PAIN	- (-) / Ongoing (.)	Mild	1	Remote	-
01-710-1021 / 79/B/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Moderate	3	Possible	-
01-710-1021 / 79/B/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Moderate	1	Possible	-
01-710-1070 / 85/W/F	GASTROINTESTINAL DISORDERS/ GASTROINTESTINAL HAEMORRHAGE/ GASTROINTESTINAL HAEMORRHAGE	- (-) / Ongoing (.)	Severe	1	None	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline High Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-710-1070 / 85/W/F	CARDIAC DISORDERS/ SUPRAVENTRICULAR EXTRASYSTOLES/ SUPRAVENTRICULAR EXTRASYSTOLES	- (-) / Ongoing (.)	Mild	3	Possible	-
01-710-1070 / 85/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Mild	3	Probable	-
01-710-1070 / 85/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-
01-710-1070 / 85/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH/ RASH	- (-) / Ongoing (.)	Mild	3	Probable	-
01-710-1070 / 85/W/F	INJURY, POISONING AND PROCEDURAL COMPLICATIONS/ HIP FRACTURE/ HIP FRACTURE	- (-) / Ongoing (.)	Severe	1	None	-
01-710-1137 / 79/B/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Mild	3	Possible	-
01-710-1137 / 79/B/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Mild	3	Possible	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline High Dose

Subject ID/ Age/Race/Se x	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-710-1137 / 79/B/F	NERVOUS SYSTEM DISORDERS/ HEADACHE/ HEADACHE	- (-) / Ongoing (.)	Mild	3	Remote	-
01-710-1137 / 79/B/F	EAR AND LABYRINTH DISORDERS/ VERTIGO/ VERTIGO	- (-) / Ongoing (.)	Moderate	3	Possible	-
01-710-1142 / 76/W/F	GASTROINTESTINAL DISORDERS/ NAUSEA/ NAUSEA	- (-) / Ongoing (.)	Mild	1	None	-
01-710-1142 / 76/W/F	CARDIAC DISORDERS/ MYOCARDIAL INFARCTION/ MYOCARDIAL INFARCTION	- (-) / Ongoing (.)	Moderate	1	Possible	-
01-710-1142 / 76/W/F	NERVOUS SYSTEM DISORDERS/ HEADACHE/ HEADACHE	- (-) / Ongoing (.)	Mild	1	Remote	-
01-710-1142 / 76/W/F	NERVOUS SYSTEM DISORDERS/ DIZZINESS/ DIZZINESS	- (-) / Ongoing (.)	Moderate	1	Remote	-
01-710-1142 / 76/W/F	NERVOUS SYSTEM DISORDERS/ SYNCOPE VASOVAGAL/ SYNCOPE VASOVAGAL	- (-) / Ongoing (.)	Moderate	1	Possible	-
01-710-1187 / 78/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE IRRITATION/ APPLICATION SITE IRRITATION	- (-) / Ongoing (.)	Mild	3	Possible	-

Copyright © DH

**Adverse Events
Safety Analysis Set**

Xanomeline High Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-710-1249 / 79/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Mild	3	Possible	-
01-710-1249 / 79/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Mild	1	Possible	-
01-710-1249 / 79/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Mild	1	Possible	-
01-710-1249 / 79/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Moderate	3	Possible	-
01-710-1278 / 81/W/M	GASTROINTESTINAL DISORDERS/ VOMITING/ VOMITING	- (-) / Ongoing (.)	Mild	1	Remote	-
01-710-1278 / 81/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE ERYTHEMA/ APPLICATION SITE ERYTHEMA	- (-) / Ongoing (.)	Mild	3	Possible	-
01-710-1278 / 81/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE ERYTHEMA/ APPLICATION SITE ERYTHEMA	- (-) / Ongoing (.)	Mild	1	Possible	-
01-710-1278 / 81/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH/ RASH	- (-) / Ongoing (.)	Mild	3	Possible	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline High Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-710-1278 / 81/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH/ RASH	- (-) / Ongoing (.)	Mild	1	Possible	-
01-710-1278 / 81/W/M	NERVOUS SYSTEM DISORDERS/ SOMNOLENCE/ SOMNOLENCE	- (-) / Ongoing (.)	Mild	1	Remote	-
01-710-1278 / 81/W/M	NERVOUS SYSTEM DISORDERS/ BURNING SENSATION/ BURNING SENSATION	- (-) / Ongoing (.)	Moderate	1	Possible	-
01-710-1354 / 73/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Mild	3	Possible	-
01-710-1354 / 73/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Mild	3	Possible	-
01-710-1408 / 80/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Mild	3	Possible	-
01-710-1408 / 80/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Mild	1	Possible	-
01-710-1408 / 80/W/M	INFECTIONS AND INFESTATIONS/ NASOPHARYNGITIS/ NASOPHARYNGITIS	- (-) / Ongoing (.)	Mild	3	None	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline High Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-710-1408 / 80/W/M	INFECTIONS AND INFESTATIONS/ NASOPHARYNGITIS/ NASOPHARYNGITIS	- (-) / Ongoing (.)	Mild	1	None	-
01-711-1012 / 67/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-
01-711-1012 / 67/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-711-1012 / 67/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Moderate	1	Probable	-
01-711-1012 / 67/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE DERMATITIS/ APPLICATION SITE DERMATITIS	- (-) / Ongoing (.)	Mild	3	Probable	-
01-711-1012 / 67/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE DERMATITIS/ APPLICATION SITE DERMATITIS	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-711-1012 / 67/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE URTICARIA/ APPLICATION SITE URTICARIA	- (-) / Ongoing (.)	Moderate	1	Probable	-
01-711-1012 / 67/W/F	INFECTIONS AND INFESTATIONS/ NASOPHARYNGITIS/ NASOPHARYNGITIS	- (-) / Ongoing (.)	Moderate	3	None	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline High Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-711-1433 / 84/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ ASTHENIA/ ASTHENIA	- (-) / Ongoing (.)	Moderate	3	Remote	-
01-711-1433 / 84/W/F	VASCULAR DISORDERS/ HYPERTENSION/ HYPERTENSION	- (-) / Ongoing (.)	Mild	3	None	-
01-711-1433 / 84/W/F	VASCULAR DISORDERS/ HYPERTENSION/ HYPERTENSION	- (-) / Ongoing (.)	Moderate	3	None	-
01-713-1141 / 79/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH PRURITIC/ RASH PRURITIC	- (-) / Ongoing (.)	Mild	3	Probable	-
01-713-1141 / 79/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH PRURITIC/ RASH PRURITIC	- (-) / Ongoing (.)	Mild	1	Probable	-
01-713-1141 / 79/W/M	MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS/ BACK PAIN/ BACK PAIN	- (-) / Ongoing (.)	Moderate	3	Remote	-
01-713-1141 / 79/W/M	PSYCHIATRIC DISORDERS/ DELIRIUM/ DELIRIUM	- (-) / Ongoing (.)	Moderate	1	Possible	-
01-713-1209 / 77/W/F	GASTROINTESTINAL DISORDERS/ ABDOMINAL PAIN/ ABDOMINAL PAIN	- (-) / Ongoing (.)	Mild	3	Possible	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline High Dose

Subject ID/ Age/Race/Se x	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-713-1209 / 77/W/F	GASTROINTESTINAL DISORDERS/ ABDOMINAL PAIN/ ABDOMINAL PAIN	- (-) / Ongoing (.)	Moderate	3	Possible	-
01-713-1209 / 77/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-
01-713-1209 / 77/W/F	NERVOUS SYSTEM DISORDERS/ DIZZINESS/ DIZZINESS	- (-) / Ongoing (.)	Mild	3	Possible	-
01-714-1288 / 77/B/M	GASTROINTESTINAL DISORDERS/ DIARRHOEA/ DIARRHOEA	- (-) / Ongoing (.)	Mild	1	Possible	-
01-714-1288 / 77/B/M	CARDIAC DISORDERS/ SINUS BRADYCARDIA/ SINUS BRADYCARDIA	- (-) / Ongoing (.)	Moderate	3	Remote	-
01-714-1288 / 77/B/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Mild	3	Probable	-
01-714-1288 / 77/B/M	INFECTIONS AND INFESTATIONS/ NASOPHARYNGITIS/ NASOPHARYNGITIS	- (-) / Ongoing (.)	Mild	1	None	-
01-714-1288 / 77/B/M	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS/ COUGH/ COUGH	- (-) / Ongoing (.)	Mild	1	None	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline High Dose

Subject ID/ Age/Race/Se x	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-714-1288 / 77/B/M	MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS/ BACK PAIN/ BACK PAIN	- (-) / Ongoing (.)	Mild	3	None	-
01-714-1288 / 77/B/M	MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS/ BACK PAIN/ BACK PAIN	- (-) / Ongoing (.)	Mild	1	None	-
01-714-1288 / 77/B/M	MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS/ ARTHRALGIA/ ARTHRALGIA	- (-) / Ongoing (.)	Moderate	3	None	-
01-714-1288 / 77/B/M	NERVOUS SYSTEM DISORDERS/ DIZZINESS/ DIZZINESS	- (-) / Ongoing (.)	Mild	1	Possible	-
01-714-1425 / 81/W/M	CARDIAC DISORDERS/ ATRIOVENTRICULAR BLOCK SECOND DEGREE/ ATRIOVENTRICULAR BLOCK SECOND DEGREE	- (-) / Ongoing (.)	Moderate	3	None	-
01-715-1319 / 65/W/M	CARDIAC DISORDERS/ SINUS BRADYCARDIA/ SINUS BRADYCARDIA	- (-) / Ongoing (.)	Moderate	1	None	-
01-715-1321 / 75/W/F	GASTROINTESTINAL DISORDERS/ NAUSEA/ NAUSEA	- (-) / Ongoing (.)	Mild	3	Remote	-
01-715-1321 / 75/W/F	GASTROINTESTINAL DISORDERS/ NAUSEA/ NAUSEA	- (-) / Ongoing (.)	Mild	1	Remote	-

Copyright © DH

**Adverse Events
Safety Analysis Set**

Xanomeline High Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-715-1321 / 75/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE REACTION/ APPLICATION SITE REACTION	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-715-1321 / 75/W/F	CARDIAC DISORDERS/ SINUS BRADYCARDIA/ SINUS BRADYCARDIA	- (-) / Ongoing (.)	Mild	3	None	-
01-716-1071 / 78/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ FATIGUE/ FATIGUE	- (-) / Ongoing (.)	Mild	3	Possible	-
01-716-1071 / 78/W/F	NERVOUS SYSTEM DISORDERS/ SYNCOPE/ SYNCOPE	- (-) / Ongoing (.)	Moderate	1	Probable	-
01-716-1071 / 78/W/F	NERVOUS SYSTEM DISORDERS/ HYPERSONMIA/ HYPERSONMIA	- (-) / Ongoing (.)	Mild	3	Possible	-
01-716-1189 / 81/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Mild	3	Possible	-
01-716-1189 / 81/W/M	PSYCHIATRIC DISORDERS/ DELUSION/ DELUSION	- (-) / Ongoing (.)	Moderate	3	None	-
01-716-1189 / 81/W/M	PSYCHIATRIC DISORDERS/ HALLUCINATION/ HALLUCINATION	- (-) / Ongoing (.)	Moderate	3	None	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline High Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-716-1189 / 81/W/M	NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS) / PROSTATE CANCER/ PROSTATE CANCER	- (-) / Ongoing (.)	Severe	3	None	-
01-716-1229 / 73/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-716-1229 / 73/W/F	INVESTIGATIONS/ BLOOD CHOLESTEROL INCREASED/ BLOOD CHOLESTEROL INCREASED	- (-) / Ongoing (.)	Mild	3	None	-
01-716-1364 / 84/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Mild	3	Probable	-
01-716-1364 / 84/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-
01-716-1373 / 74/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-716-1373 / 74/W/M	NERVOUS SYSTEM DISORDERS/ COGNITIVE DISORDER/ COGNITIVE DISORDER	- (-) / Ongoing (.)	Mild	3	None	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline High Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-716-1418 / 80/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Mild	3	Probable	-
01-716-1418 / 80/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-
01-716-1418 / 80/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ URTICARIA/ URTICARIA	- (-) / Ongoing (.)	Mild	3	Probable	-
01-716-1418 / 80/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ URTICARIA/ URTICARIA	- (-) / Ongoing (.)	Mild	1	Probable	-
01-716-1418 / 80/W/F	EYE DISORDERS/ VISION BLURRED/ VISION BLURRED	- (-) / Ongoing (.)	Moderate	3	Possible	-
01-716-1418 / 80/W/F	EYE DISORDERS/ VISION BLURRED/ VISION BLURRED	- (-) / Ongoing (.)	Moderate	1	Possible	-
01-716-1418 / 80/W/F	NERVOUS SYSTEM DISORDERS/ HEADACHE/ HEADACHE	- (-) / Ongoing (.)	Moderate	3	Possible	-
01-716-1418 / 80/W/F	NERVOUS SYSTEM DISORDERS/ HEADACHE/ HEADACHE	- (-) / Ongoing (.)	Moderate	1	Possible	-
01-716-1418 / 80/W/F	NERVOUS SYSTEM DISORDERS/ HEADACHE/ HEADACHE	- (-) / Ongoing (.)	Mild	3	Possible	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline High Dose

Subject ID/ Age/Race/Se x	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-716-1418 / 80/W/F	NERVOUS SYSTEM DISORDERS/ HEADACHE/ HEADACHE	- (-) / Ongoing (.)	Mild	1	Possible	-
01-716-1447 / 72/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ CHEST PAIN/ CHEST PAIN	- (-) / Ongoing (.)	Mild	1	Remote	-
01-716-1447 / 72/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ ERYTHEMA/ ERYTHEMA	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-716-1447 / 72/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-716-1447 / 72/W/F	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ HYPERHIDROSIS/ HYPERHIDROSIS	- (-) / Ongoing (.)	Mild	3	Possible	-
01-716-1447 / 72/W/F	INVESTIGATIONS/ ELECTROCARDIOGRAM T WAVE INVERSION/ ELECTROCARDIOGRAM T WAVE INVERSION	- (-) / Ongoing (.)	Mild	3	Possible	-
01-717-1109 / 84/W/M	CARDIAC DISORDERS/ VENTRICULAR EXTRASYSTOLES/ VENTRICULAR EXTRASYSTOLES	- (-) / Ongoing (.)	Mild	3	None	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline High Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-717-1109 / 84/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ HYPERHIDROSIS/ HYPERHIDROSIS	- (-) / Ongoing (.)	Mild	1	Possible	-
01-717-1109 / 84/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ SKIN IRRITATION/ SKIN IRRITATION	- (-) / Ongoing (.)	Mild	3	Probable	-
01-717-1109 / 84/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS GENERALISED/ PRURITUS GENERALISED	- (-) / Ongoing (.)	Mild	3	Probable	-
01-717-1109 / 84/W/M	METABOLISM AND NUTRITION DISORDERS/ INCREASED APPETITE/ INCREASED APPETITE	- (-) / Ongoing (.)	Mild	3	Remote	-
01-717-1109 / 84/W/M	METABOLISM AND NUTRITION DISORDERS/ INCREASED APPETITE/ INCREASED APPETITE	- (-) / Ongoing (.)	Mild	1	Remote	-
01-717-1109 / 84/W/M	PSYCHIATRIC DISORDERS/ INSOMNIA/ INSOMNIA	- (-) / Ongoing (.)	Mild	3	Possible	-
01-717-1109 / 84/W/M	PSYCHIATRIC DISORDERS/ CONFUSIONAL STATE/ CONFUSIONAL STATE	- (-) / Ongoing (.)	Mild	3	Remote	-
01-717-1174 / 73/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Mild	3	Probable	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline High Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-717-1174 / 73/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ PRURITUS/ PRURITUS	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-717-1174 / 73/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ RASH/ RASH	- (-) / Ongoing (.)	Severe	1	Remote	-
01-717-1174 / 73/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ SKIN IRRITATION/ SKIN IRRITATION	- (-) / Ongoing (.)	Mild	3	Probable	-
01-717-1174 / 73/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ SKIN IRRITATION/ SKIN IRRITATION	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-717-1174 / 73/W/M	PSYCHIATRIC DISORDERS/ INSOMNIA/ INSOMNIA	- (-) / Ongoing (.)	Mild	1	Possible	-
01-717-1357 / 77/W/M	GASTROINTESTINAL DISORDERS/ NAUSEA/ NAUSEA	- (-) / Ongoing (.)	Mild	1	Remote	-
01-717-1357 / 77/W/M	GASTROINTESTINAL DISORDERS/ VOMITING/ VOMITING	- (-) / Ongoing (.)	Moderate	1	Remote	-
01-717-1357 / 77/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ OEDEMA PERIPHERAL/ OEDEMA PERIPHERAL	- (-) / Ongoing (.)	Moderate	3	Possible	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline High Dose

Subject ID/ Age/Race/Se x	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-717-1357 / 77/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PERSPIRATION/ APPLICATION SITE PERSPIRATION	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-717-1357 / 77/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PERSPIRATION/ APPLICATION SITE PERSPIRATION	- (-) / Ongoing (.)	Moderate	1	Probable	-
01-717-1357 / 77/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ SKIN IRRITATION/ SKIN IRRITATION	- (-) / Ongoing (.)	Mild	3	Probable	-
01-717-1357 / 77/W/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ SKIN IRRITATION/ SKIN IRRITATION	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-717-1357 / 77/W/M	NERVOUS SYSTEM DISORDERS/ DIZZINESS/ DIZZINESS	- (-) / Ongoing (.)	Moderate	3	None	-
01-717-1357 / 77/W/M	NERVOUS SYSTEM DISORDERS/ DIZZINESS/ DIZZINESS	- (-) / Ongoing (.)	Moderate	1	Remote	-
01-718-1101 / 82/B/M	GASTROINTESTINAL DISORDERS/ VOMITING/ VOMITING	- (-) / Ongoing (.)	Mild	1	None	-
01-718-1101 / 82/B/M	CARDIAC DISORDERS/ MYOCARDIAL INFARCTION/ MYOCARDIAL INFARCTION	- (-) / Ongoing (.)	Mild	3	None	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline High Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-718-1101 / 82/B/M	CARDIAC DISORDERS/ SINUS BRADYCARDIA/ SINUS BRADYCARDIA	- (-) / Ongoing (.)	Mild	3	None	-
01-718-1101 / 82/B/M	CARDIAC DISORDERS/ SINUS BRADYCARDIA/ SINUS BRADYCARDIA	- (-) / Ongoing (.)	Mild	1	None	-
01-718-1101 / 82/B/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ HYPERHIDROSIS/ HYPERHIDROSIS	- (-) / Ongoing (.)	Mild	3	Possible	-
01-718-1101 / 82/B/M	SKIN AND SUBCUTANEOUS TISSUE DISORDERS/ HYPERHIDROSIS/ HYPERHIDROSIS	- (-) / Ongoing (.)	Mild	1	Possible	-
01-718-1328 / 86/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE IRRITATION/ APPLICATION SITE IRRITATION	- (-) / Ongoing (.)	Mild	1	Probable	-
01-718-1328 / 86/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE IRRITATION/ APPLICATION SITE IRRITATION	- (-) / Ongoing (.)	Mild	3	Probable	-
01-718-1328 / 86/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE IRRITATION/ APPLICATION SITE IRRITATION	- (-) / Ongoing (.)	Moderate	1	Probable	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline High Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-718-1328 / 86/W/M	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE DERMATITIS/ APPLICATION SITE DERMATITIS	- (-) / Ongoing (.)	Mild	1	Probable	-
01-718-1371 / 69/W/F	GASTROINTESTINAL DISORDERS/ NAUSEA/ NAUSEA	- (-) / Ongoing (.)	Mild	1	Possible	-
01-718-1371 / 69/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE IRRITATION/ APPLICATION SITE IRRITATION	- (-) / Ongoing (.)	Mild	3	Probable	-
01-718-1371 / 69/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE IRRITATION/ APPLICATION SITE IRRITATION	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-718-1371 / 69/W/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ FATIGUE/ FATIGUE	- (-) / Ongoing (.)	Mild	1	Possible	-
01-718-1371 / 69/W/F	NERVOUS SYSTEM DISORDERS/ PARTIAL SEIZURES WITH SECONDARY GENERALISATION/ PARTIAL SEIZURES WITH SECONDARY GENERALISATION	- (-) / Ongoing (.)	Severe	1	None	-
01-718-1371 / 69/W/F	PSYCHIATRIC DISORDERS/ HALLUCINATION, VISUAL/ HALLUCINATION, VISUAL	- (-) / Ongoing (.)	Moderate	1	Possible	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline High Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-718-1427 / 74/B/F	GASTROINTESTINAL DISORDERS/ NAUSEA/ NAUSEA	- (-) / Ongoing (.)	Moderate	1	Remote	-
01-718-1427 / 74/B/F	GASTROINTESTINAL DISORDERS/ NAUSEA/ NAUSEA	- (-) / Ongoing (.)	Moderate	1	Possible	-
01-718-1427 / 74/B/F	GASTROINTESTINAL DISORDERS/ NAUSEA/ NAUSEA	- (-) / Ongoing (.)	Moderate	1	Possible	-
01-718-1427 / 74/B/F	GASTROINTESTINAL DISORDERS/ NAUSEA/ NAUSEA	- (-) / Ongoing (.)	Severe	1	Probable	-
01-718-1427 / 74/B/F	GASTROINTESTINAL DISORDERS/ NAUSEA/ NAUSEA	- (-) / Ongoing (.)	Moderate	3	Possible	-
01-718-1427 / 74/B/F	GASTROINTESTINAL DISORDERS/ NAUSEA/ NAUSEA	- (-) / Ongoing (.)	Moderate	1	Possible	-
01-718-1427 / 74/B/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Moderate	3	Probable	-
01-718-1427 / 74/B/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE PRURITUS/ APPLICATION SITE PRURITUS	- (-) / Ongoing (.)	Moderate	1	Probable	-
01-718-1427 / 74/B/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE DERMATITIS/ APPLICATION SITE DERMATITIS	- (-) / Ongoing (.)	Moderate	1	Probable	-

Copyright © DH

Adverse Events
Safety Analysis Set

Xanomeline High Dose

Subject ID/ Age/Race/Sex	MedDRA SOC/ Preferred Term/ Verbatim Term/	Start Date (Day) / Stop Date (Day)	Severity	Outcome ^a	Related	Action ^b
01-718-1427 / 74/B/F	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS/ APPLICATION SITE DERMATITIS/ APPLICATION SITE DERMATITIS	- (-) / Ongoing (.)	Mild	3	Probable	-
01-718-1427 / 74/B/F	METABOLISM AND NUTRITION DISORDERS/ DECREASED APPETITE/ DECREASED APPETITE	- (-) / Ongoing (.)	Moderate	3	Possible	-
01-718-1427 / 74/B/F	METABOLISM AND NUTRITION DISORDERS/ DECREASED APPETITE/ DECREASED APPETITE	- (-) / Ongoing (.)	Moderate	1	Possible	-
01-718-1427 / 74/B/F	MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS/ BACK PAIN/ BACK PAIN	- (-) / Ongoing (.)	Mild	1	None	-
01-718-1427 / 74/B/F	NERVOUS SYSTEM DISORDERS/ LETHARGY/ LETHARGY	- (-) / Ongoing (.)	Moderate	1	Possible	-
01-718-1427 / 74/B/F	NERVOUS SYSTEM DISORDERS/ AMNESIA/ AMNESIA	- (-) / Ongoing (.)	Mild	3	None	-
01-718-1427 / 74/B/F	NERVOUS SYSTEM DISORDERS/ AMNESIA/ AMNESIA	- (-) / Ongoing (.)	Mild	1	None	-

Copyright © DH