AE Prevelance (6% or greater)

Infections and infestations		Treatment	Control	
Upper respiratory tract infection 216 (61.7%) 0 (0.0%) △ ○		(n=350)	(n=350)	0 20 40 60 80 100
-Gastroenteritis	Infections and infestations	314 (89.7%)	0 (0.0%)	Δ Ο
-Varicella -Lower respiratory tract infection 97 (27.7%) 0 (0.0%) △ ○ -Nasopharyngitis 95 (27.1%) 0 (0.0%) △ ○ -Raintitis 93 (26.5%) 0 (0.0%) △ ○ -Ear infection 92 (26.3%) 0 (0.0%) △ ○ -Thinitis 93 (26.5%) 0 (0.0%) △ ○ -Ear infection 92 (26.3%) 0 (0.0%) △ ○ -Viral infection -Viral skin infection -Viral skin infection -Viral upper respiratory tract infection -Vir	Upper respiratory tract infection	216 (61.7%)	0 (0.0%)	Δ O
-Varicella -Lower respiratory tract infection 97 (27.7%) 0 (0.0%) △ ○ -Nasopharyngitis 95 (27.1%) 0 (0.0%) △ ○ -Raintitis 93 (26.5%) 0 (0.0%) △ ○ -Ear infection 92 (26.3%) 0 (0.0%) △ ○ -Thinitis 93 (26.5%) 0 (0.0%) △ ○ -Ear infection 92 (26.3%) 0 (0.0%) △ ○ -Viral infection -Viral skin infection -Viral skin infection -Viral upper respiratory tract infection -Vir	-Gastroenteritis	195 (55.7%)	0 (0.0%)	Δ
-Tonsillitis	-Varicella	134 (38.3%)	0 (0.0%)	Δ ο
-Tonsillitis	Lower respiratory tract infection	97 (27.7%)	0 (0.0%)	Δ O
-Tonsillitis	-Nasopharyngitis	95 (27.1%)	0 (0.0%)	Δ O
-Tonsillitis	-Rhinitis	93 (26.6%)	0 (0.0%)	Δ Ο
-Tonsillitis	-Ear infection	92 (26.3%)	0 (0.0%)	Δ Ο
-Eczema infected	-Viral infection	52 (14.9%)	0 (0.0%)	
-Eczema infected	-Tonsillitis	47 (13.4%)	0 (0.0%)	Δ O
-Eczema infected	–Viral skin infection	46 (13.1%)	0 (0.0%)	Δ O
-Otitis media	Viral upper respiratory tract infection	37 (10.6%)	0 (0.0%)	Δ O
-Influenza	-Eczema infected	24 (6.9%)	0 (0.0%)	Δο
Skin and subcutaneous tissue	-Otitis media	24 (6.9%)	0 (0.0%)	ΔO
-Eczema	-Influenza	21 (6.0%)	0 (0.0%)	$\triangle \circ$
-Urticaria -Rash 32 (9.1%) 0 (0.0%) △ ○	Skin and subcutaneous tissue	209 (59.7%)	0 (0.0%)	\triangle
-Rash 32 (9.1%) 0 (0.0%)	-Eczema	148 (42.3%)	0 (0.0%)	Δ O
Rash 32 (9.1%) 0 (0.0%) △	-Urticaria	67 (19.1%)	0 (0.0%)	\triangle \Diamond
-Food allergy	-Rash	32 (9.1%)	0 (0.0%)	
-Milk allergy -Seasonal allergy -Seasonal allergy -Hypersensitivity 21 (6.0%) 0 (0.0%) △ ○ -Hypersensitivity 21 (6.0%) 0 (0.0%) △ ○ -Hypersensitivity 21 (6.0%) 0 (0.0%) △ ○ -Vomiting 73 (20.9%) 0 (0.0%) △ ○ -Constipation 25 (7.1%) 0 (0.0%) △ ○ -Constipation 25 (7.1%) 0 (0.0%) △ ○ -Constipation 25 (7.1%) 0 (0.0%) △ ○ -Wheezing -Asthma -Cough -Asthma -S3 (15.1%) 0 (0.0%) △ ○ -Cough 42 (12.0%) 0 (0.0%) △ ○ -Pyrexia -Pyrexia -Congh -Conginctivitis -Conginctivit	Immune system	183 (52.3%)	0 (0.0%)	Δ Ο
-Seasonal allergy 33 (9.4%) 0 (0.0%)	-Food allergy	146 (41.7%)	0 (0.0%)	Δ ο
	–Milk allergy	36 (10.3%)	0 (0.0%)	Δ O
Gastrointestinal	-Seasonal allergy	33 (9.4%)	0 (0.0%)	Δ O
-Vomiting 73 (20.9%) 0 (0.0%)	-Hypersensitivity	21 (6.0%)	0 (0.0%)	$\triangle \circ$
- Diarrhoea	Gastrointestinal	141 (40.3%)	0 (0.0%)	Δ
Constipation 25 (7.1%) 0 (0.0%) △ ○	-Vomiting	73 (20.9%)	0 (0.0%)	Δ •
Respiratory, thoracic and mediastinal 116 (33.1%) 0 (0.0%) △ ○ -Wheezing 71 (20.3%) 0 (0.0%) △ ○ -Asthma 53 (15.1%) 0 (0.0%) △ ○ -Cough 42 (12.0%) 0 (0.0%) △ ○ -Pyrexia 86 (24.6%) 0 (0.0%) △ ○ -Pyrexia 86 (24.6%) 0 (0.0%) △ ○ -Conjunctivitis 45 (12.9%) 0 (0.0%) △ ○ -Conjunctivitis 45 (12.9%) 0 (0.0%) △ ○ Injury, poisoning and procedural complications 40 (11.4%) 0 (0.0%) △ ○ Metabolism and nutrition 14 (4.0%) 0 (0.0%) △ ○ Blood and lymphatic system 5 (1.4%) 0 (0.0%) △ ○ Nervous system 5 (1.4%) 0 (0.0%) △ ○ Congenital, familial and genetic 4 (1.1%) 0 (0.0%) △ Ear and labyrinth 4 (1.1%) 0 (0.0%) △ <t< th=""><th>-Diarrhoea</th><th>60 (17.1%)</th><th>0 (0.0%)</th><th>Δ 0</th></t<>	-Diarrhoea	60 (17.1%)	0 (0.0%)	Δ 0
-Wheezing 71 (20.3%) 0 (0.0%)	-Constipation	25 (7.1%)	0 (0.0%)	
-Asthma -Cough 42 (12.0%) 0 (0.0%) △ ○ General disorders and administration site conditions 94 (26.9%) 0 (0.0%) △ ○ -Pyrexia 86 (24.6%) 0 (0.0%) △ ○ Eye -Conjunctivitis 45 (12.9%) 0 (0.0%) △ ○ Injury, poisoning and procedural complications 40 (11.4%) 0 (0.0%) △ ○ Metabolism and nutrition 14 (4.0%) 0 (0.0%) △ ○ Blood and lymphatic system 5 (1.4%) 0 (0.0%) △ ○ Nervous system 5 (1.4%) 0 (0.0%) △ ○ Congenital, familial and genetic 4 (1.1%) 0 (0.0%) △ ○ Ear and labyrinth 4 (1.1%) 0 (0.0%) △ ○ Investigations 1 (0.3%) 0 (0.0%) △ ○ Musculoskeletal and connective tissue 1 (0.3%) 0 (0.0%) △ ○ Neoplasms benign, malignant and unspecified (incl cy 1 (0.3%) 0 (0.0%) △	Respiratory, thoracic and mediastinal	116 (33.1%)	0 (0.0%)	<u> </u>
Cough	-Wheezing	71 (20.3%)	0 (0.0%)	\triangle \Diamond
General disorders and administration site conditions 94 (26.9%) 0 (0.0%) △ ○ -Pyrexia 86 (24.6%) 0 (0.0%) △ ○ Eye 53 (15.1%) 0 (0.0%) △ ○ -Conjunctivitis 45 (12.9%) 0 (0.0%) △ ○ Injury, poisoning and procedural complications 40 (11.4%) 0 (0.0%) △ ○ Metabolism and nutrition 14 (4.0%) 0 (0.0%) △ ○ Blood and lymphatic system 5 (1.4%) 0 (0.0%) △ ○ Nervous system 5 (1.4%) 0 (0.0%) △ ○ Congenital, familial and genetic 4 (1.1%) 0 (0.0%) △ ○ Ear and labyrinth 4 (1.1%) 0 (0.0%) △ ○ Cardiac 1 (0.3%) 0 (0.0%) △ ○ Investigations 1 (0.3%) 0 (0.0%) △ ○ Musculoskeletal and connective tissue 1 (0.3%) 0 (0.0%) △ Neoplasms benign, malignant and unspecified (incl cy 1 (0.3%) 0	-Asthma	53 (15.1%)	0 (0.0%)	A O
—Pyrexia 86 (24.6%) 0 (0.0%) △ ○ Eye 53 (15.1%) 0 (0.0%) △ ○ —Conjunctivitis 45 (12.9%) 0 (0.0%) △ ○ Injury, poisoning and procedural complications 40 (11.4%) 0 (0.0%) △ ○ Metabolism and nutrition 14 (4.0%) 0 (0.0%) △ ○ Blood and lymphatic system 5 (1.4%) 0 (0.0%) △ ○ Nervous system 5 (1.4%) 0 (0.0%) △ ○ Congenital, familial and genetic 4 (1.1%) 0 (0.0%) △ ○ Ear and labyrinth 4 (1.1%) 0 (0.0%) △ ○ Cardiac 1 (0.3%) 0 (0.0%) △ ○ Investigations 1 (0.3%) 0 (0.0%) △ ○ Musculoskeletal and connective tissue 1 (0.3%) 0 (0.0%) △ Neoplasms benign, malignant and unspecified (incl cy 1 (0.3%) 0 (0.0%) △	–Cough	42 (12.0%)	0 (0.0%)	
Eye	General disorders and administration site conditions	94 (26.9%)	0 (0.0%)	<u> </u>
—Conjunctivitis 45 (12.9%) 0 (0.0%) □ Injury, poisoning and procedural complications 40 (11.4%) 0 (0.0%) □ Metabolism and nutrition 14 (4.0%) 0 (0.0%) □ Blood and lymphatic system 5 (1.4%) 0 (0.0%) □ Nervous system 5 (1.4%) 0 (0.0%) □ Congenital, familial and genetic 4 (1.1%) 0 (0.0%) □ Ear and labyrinth 4 (1.1%) 0 (0.0%) □ Cardiac 1 (0.3%) 0 (0.0%) □ Investigations 1 (0.3%) 0 (0.0%) □ Musculoskeletal and connective tissue 1 (0.3%) 0 (0.0%) □ Neoplasms benign, malignant and unspecified (incl cy 1 (0.3%) 0 (0.0%) □	-Pyrexia	86 (24.6%)	0 (0.0%)	
Injury, poisoning and procedural complications 40 (11.4%) 0 (0.0%) Metabolism and nutrition 14 (4.0%) 0 (0.0%) Blood and lymphatic system 5 (1.4%) 0 (0.0%) Nervous system 5 (1.4%) 0 (0.0%) Congenital, familial and genetic 4 (1.1%) 0 (0.0%) Ear and labyrinth 4 (1.1%) 0 (0.0%) Cardiac 1 (0.3%) 0 (0.0%) Investigations 1 (0.3%) 0 (0.0%) Musculoskeletal and connective tissue 1 (0.3%) 0 (0.0%) Neoplasms benign, malignant and unspecified (incl cy 1 (0.3%) 0 (0.0%)	Eye	53 (15.1%)	0 (0.0%)	<u> </u>
Metabolism and nutrition 14 (4.0%) 0 (0.0%) ✓ Blood and lymphatic system 5 (1.4%) 0 (0.0%) ✓ Nervous system 5 (1.4%) 0 (0.0%) ✓ Congenital, familial and genetic 4 (1.1%) 0 (0.0%) ✓ Ear and labyrinth 4 (1.1%) 0 (0.0%) ✓ Cardiac 1 (0.3%) 0 (0.0%) ✓ Investigations 1 (0.3%) 0 (0.0%) ✓ Musculoskeletal and connective tissue 1 (0.3%) 0 (0.0%) ✓ Neoplasms benign, malignant and unspecified (incl cy 1 (0.3%) 0 (0.0%) ✓		45 (12.9%)	0 (0.0%)	
Blood and lymphatic system 5 (1.4%) 0 (0.0%) △		40 (11.4%)	0 (0.0%)	
Nervous system 5 (1.4%) 0 (0.0%) ♠ Congenital, familial and genetic 4 (1.1%) 0 (0.0%) ♠ Ear and labyrinth 4 (1.1%) 0 (0.0%) ♠ Cardiac 1 (0.3%) 0 (0.0%) ♠ Investigations 1 (0.3%) 0 (0.0%) ♠ Musculoskeletal and connective tissue 1 (0.3%) 0 (0.0%) ♠ Neoplasms benign, malignant and unspecified (incl cy 1 (0.3%) 0 (0.0%) ♠	Metabolism and nutrition	14 (4.0%)	0 (0.0%)	
Congenital, familial and genetic 4 (1.1%) 0 (0.0%) ♠ Ear and labyrinth 4 (1.1%) 0 (0.0%) ♠ Cardiac 1 (0.3%) 0 (0.0%) ♠ Investigations 1 (0.3%) 0 (0.0%) ♠ Musculoskeletal and connective tissue 1 (0.3%) 0 (0.0%) ♠ Neoplasms benign, malignant and unspecified (incl cy 1 (0.3%) 0 (0.0%) ♠		5 (1.4%)	0 (0.0%)	
Ear and labyrinth 4 (1.1%) 0 (0.0%)		5 (1.4%)	0 (0.0%)	
Cardiac 1 (0.3%) 0 (0.0%) ♠ Investigations 1 (0.3%) 0 (0.0%) ♠ Musculoskeletal and connective tissue 1 (0.3%) 0 (0.0%) ♠ Neoplasms benign, malignant and unspecified (incl cy 1 (0.3%) 0 (0.0%) ♠		4 (1.1%)	0 (0.0%)	
Investigations 1 (0.3%) 0 (0.0%) Musculoskeletal and connective tissue 1 (0.3%) 0 (0.0%) Neoplasms benign, malignant and unspecified (incl cy1 (0.3%) 0 (0.0%) Output Description:		, ,	0 (0.0%)	
Musculoskeletal and connective tissue 1 (0.3%) 0 (0.0%) Neoplasms benign, malignant and unspecified (incl cy 1 (0.3%) 0 (0.0%)		1 (0.3%)		
Neoplasms benign, malignant and unspecified (incl cy1 (0.3%) 0 (0.0%)	Investigations	1 (0.3%)	0 (0.0%)	
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		, ,	0 (0.0%)	
Reproductive system and breast 1 (0.3%) 0 (0.0%)		,	,	
Psychiatric 0 (0.0%) 0 (0.0%)	Psychiatric	0 (0.0%)	0 (0.0%)	Φ