

Table 1.0  
Adverse Events by Severity  
Safety Population

System Organ Class Preferred Term	ARM A (N=30)		
	Mild	Mod**	Severe
All System Organ Classes			
All Adverse Events	22 ( 73.3%)	8 ( 26.7%)	0 ( 0.0%)
Gastrointestinal disorders			
Cheilitis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Diarrhoea	1 ( 3.3%)	0 ( 0.0%)	0 ( 0.0%)
Stomach Discomfort	1 ( 3.3%)	0 ( 0.0%)	0 ( 0.0%)
Toothache	1 ( 3.3%)	0 ( 0.0%)	0 ( 0.0%)
General disorders and administration site conditions			
Application Site Erythema	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Influenza Like Illness	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Hepatobiliary disorders			
Gallbladder Disorder	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Infections and infestations			
Bronchitis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Nail Infection	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Paronychia	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Rash Pustular	1 ( 3.3%)	0 ( 0.0%)	0 ( 0.0%)
Respiratory Tract Infection	1 ( 3.3%)	0 ( 0.0%)	0 ( 0.0%)
Rhinitis	0 ( 0.0%)	1 ( 3.3%)	0 ( 0.0%)
Sinusitis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

Date Produced: Time ; Program: Table3\_0.R

\* Total Reporting is defined as number of subjects who reported at least one adverse event.

\*\* Mod = Moderate

# Episodes is defined as the total number of occurrences of adverse events

% is defined as Number of Subjects divided by Total Reporting

Note: Adverse events were coded using MedDRA Version 9.1

Table 1.0  
Adverse Events by Severity  
Safety Population

System Organ Class Preferred Term	ARM B (N=19)		
	Mild	Mod**	Severe
All System Organ Classes			
All Adverse Events	9 ( 47.4%)	10 ( 52.6%)	0 ( 0.0%)
Gastrointestinal disorders			
Cheilitis	0 ( 0.0%)	1 ( 5.3%)	0 ( 0.0%)
Diarrhoea	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Stomach Discomfort	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Toothache	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
General disorders and administration site conditions			
Application Site Erythema	1 ( 5.3%)	0 ( 0.0%)	0 ( 0.0%)
Influenza Like Illness	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Hepatobiliary disorders			
Gallbladder Disorder	0 ( 0.0%)	1 ( 5.3%)	0 ( 0.0%)
Infections and infestations			
Bronchitis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Nail Infection	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Paronychia	0 ( 0.0%)	1 ( 5.3%)	0 ( 0.0%)
Rash Pustular	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Respiratory Tract Infection	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Rhinitis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Sinusitis	1 ( 5.3%)	0 ( 0.0%)	0 ( 0.0%)

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Table 1.0  
Adverse Events by Severity  
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System Organ Class Preferred Term	ARM C (N=10)		
	Mild	Mod**	Severe
All System Organ Classes			
All Adverse Events	4 ( 40.0%)	6 ( 60.0%)	0 ( 0.0%)
Gastrointestinal disorders			
Cheilitis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Diarrhoea	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Stomach Discomfort	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Toothache	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
General disorders and administration site conditions			
Application Site Erythema	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Influenza Like Illness	1 ( 10.0%)	0 ( 0.0%)	0 ( 0.0%)
Hepatobiliary disorders			
Gallbladder Disorder	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Infections and infestations			
Bronchitis	0 ( 0.0%)	2 ( 20.0%)	0 ( 0.0%)
Nail Infection	0 ( 0.0%)	1 ( 10.0%)	0 ( 0.0%)
Paronychia	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Rash Pustular	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Respiratory Tract Infection	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Rhinitis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Sinusitis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

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Table 1.0  
Adverse Events by Severity  
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System Organ Class Preferred Term	ARM D (N=16)		
	Mild	Mod**	Severe
All System Organ Classes			
All Adverse Events	7 ( 43.8%)	8 ( 50.0%)	1 ( 6.2%)
Gastrointestinal disorders			
Cheilitis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Diarrhoea	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Stomach Discomfort	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Toothache	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
General disorders and administration site conditions			
Application Site Erythema	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Influenza Like Illness	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Hepatobiliary disorders			
Gallbladder Disorder	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Infections and infestations			
Bronchitis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Nail Infection	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Paronychia	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Rash Pustular	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Respiratory Tract Infection	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Rhinitis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Sinusitis	0 ( 0.0%)	1 ( 6.2%)	0 ( 0.0%)

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Safety Population

System Organ Class Preferred Term	ARM A (N=30)		
	Mild	Mod**	Severe
Tinea Pedis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Upper Respiratory Fungal Infection	0 ( 0.0%)	1 ( 3.3%)	0 ( 0.0%)
Upper Respiratory Tract Infection	1 ( 3.3%)	0 ( 0.0%)	0 ( 0.0%)
Urinary Tract Infection	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Wound Infection	0 ( 0.0%)	1 ( 3.3%)	0 ( 0.0%)
Injury, poisoning and procedural complications			
Fall	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Heat Cramps	1 ( 3.3%)	0 ( 0.0%)	0 ( 0.0%)
Muscle Injury	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Procedural Pain	0 ( 0.0%)	1 ( 3.3%)	0 ( 0.0%)
Investigations			
Blood Potassium Decreased	0 ( 0.0%)	1 ( 3.3%)	0 ( 0.0%)
Blood Triglycerides Increased	1 ( 3.3%)	0 ( 0.0%)	0 ( 0.0%)
Vitamin D Decreased	1 ( 3.3%)	0 ( 0.0%)	0 ( 0.0%)
Musculoskeletal and connective tissue disorders			
Back Pain	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Joint Swelling	0 ( 0.0%)	1 ( 3.3%)	0 ( 0.0%)
Myalgia	0 ( 0.0%)	1 ( 3.3%)	0 ( 0.0%)
Pain In Extremity	1 ( 3.3%)	0 ( 0.0%)	0 ( 0.0%)

Nervous system disorders

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Safety Population

System Organ Class Preferred Term	ARM B (N=19)		
	Mild	Mod**	Severe
Tinea Pedis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Upper Respiratory Fungal Infection	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Upper Respiratory Tract Infection	2 ( 10.5%)	0 ( 0.0%)	0 ( 0.0%)
Urinary Tract Infection	0 ( 0.0%)	2 ( 10.5%)	0 ( 0.0%)
Wound Infection	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Injury, poisoning and procedural complications			
Fall	1 ( 5.3%)	0 ( 0.0%)	0 ( 0.0%)
Heat Cramps	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Muscle Injury	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Procedural Pain	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Investigations			
Blood Potassium Decreased	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Blood Triglycerides Increased	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Vitamin D Decreased	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Musculoskeletal and connective tissue disorders			
Back Pain	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Joint Swelling	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Myalgia	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Pain In Extremity	0 ( 0.0%)	1 ( 5.3%)	0 ( 0.0%)

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Table 1.0  
Adverse Events by Severity  
Safety Population

System Organ Class Preferred Term	ARM C (N=10)		
	Mild	Mod**	Severe
Tinea Pedis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Upper Respiratory Fungal Infection	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Upper Respiratory Tract Infection	2 ( 20.0%)	0 ( 0.0%)	0 ( 0.0%)
Urinary Tract Infection	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Wound Infection	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Injury, poisoning and procedural complications			
Fall	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Heat Cramps	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Muscle Injury	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Procedural Pain	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Investigations			
Blood Potassium Decreased	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Blood Triglycerides Increased	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Vitamin D Decreased	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Musculoskeletal and connective tissue disorders			
Back Pain	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Joint Swelling	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Myalgia	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Pain In Extremity	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

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System Organ Class Preferred Term	ARM D (N=16)		
	Mild	Mod**	Severe
Tinea Pedis	0 ( 0.0%)	1 ( 6.2%)	0 ( 0.0%)
Upper Respiratory Fungal Infection	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Upper Respiratory Tract Infection	1 ( 6.2%)	0 ( 0.0%)	0 ( 0.0%)
Urinary Tract Infection	0 ( 0.0%)	1 ( 6.2%)	0 ( 0.0%)
Wound Infection	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Injury, poisoning and procedural complications			
Fall	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Heat Cramps	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Muscle Injury	0 ( 0.0%)	1 ( 6.2%)	0 ( 0.0%)
Procedural Pain	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Investigations			
Blood Potassium Decreased	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Blood Triglycerides Increased	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Vitamin D Decreased	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Musculoskeletal and connective tissue disorders			
Back Pain	1 ( 6.2%)	0 ( 0.0%)	0 ( 0.0%)
Joint Swelling	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Myalgia	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Pain In Extremity	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

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Safety Population

System Organ Class Preferred Term	ARM A (N=30)		
	Mild	Mod**	Severe
Burning Sensation	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Dizziness	1 ( 3.3%)	0 ( 0.0%)	0 ( 0.0%)
Headache	10 ( 33.3%)	1 ( 3.3%)	0 ( 0.0%)
Sciatica	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Reproductive system and breast disorders			
Menstrual Discomfort	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Respiratory, thoracic and mediastinal disorders			
Cough	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Nasal Congestion	1 ( 3.3%)	0 ( 0.0%)	0 ( 0.0%)
Sinus Congestion	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Throat Irritation	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Upper Respiratory Tract Congestion	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Skin and subcutaneous tissue disorders			
Erythema	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Pruritus	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Skin Discomfort	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Surgical and medical procedures			
Cholecystectomy	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Skin Lesion Excision	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

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System Organ Class Preferred Term	ARM B (N=19)		
	Mild	Mod**	Severe
Burning Sensation	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Dizziness	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Headache	1 ( 5.3%)	1 ( 5.3%)	0 ( 0.0%)
Sciatica	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Reproductive system and breast disorders			
Menstrual Discomfort	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Respiratory, thoracic and mediastinal disorders			
Cough	0 ( 0.0%)	1 ( 5.3%)	0 ( 0.0%)
Nasal Congestion	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Sinus Congestion	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Throat Irritation	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Upper Respiratory Tract Congestion	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Skin and subcutaneous tissue disorders			
Erythema	2 ( 10.5%)	0 ( 0.0%)	0 ( 0.0%)
Pruritus	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Skin Discomfort	1 ( 5.3%)	0 ( 0.0%)	0 ( 0.0%)
Surgical and medical procedures			
Cholecystectomy	0 ( 0.0%)	1 ( 5.3%)	0 ( 0.0%)
Skin Lesion Excision	0 ( 0.0%)	1 ( 5.3%)	0 ( 0.0%)

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Table 1.0  
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Safety Population

System Organ Class Preferred Term	ARM C (N=10)		
	Mild	Mod**	Severe
Burning Sensation	1 ( 10.0%)	0 ( 0.0%)	0 ( 0.0%)
Dizziness	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Headache	0 ( 0.0%)	1 ( 10.0%)	0 ( 0.0%)
Sciatica	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Reproductive system and breast disorders			
Menstrual Discomfort	0 ( 0.0%)	1 ( 10.0%)	0 ( 0.0%)
Respiratory, thoracic and mediastinal disorders			
Cough	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Nasal Congestion	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Sinus Congestion	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Throat Irritation	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Upper Respiratory Tract Congestion	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Skin and subcutaneous tissue disorders			
Erythema	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Pruritus	0 ( 0.0%)	1 ( 10.0%)	0 ( 0.0%)
Skin Discomfort	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Surgical and medical procedures			
Cholecystectomy	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Skin Lesion Excision	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

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Table 1.0  
Adverse Events by Severity  
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System Organ Class Preferred Term	ARM D (N=16)		
	Mild	Mod**	Severe
Burning Sensation	0 ( 0.0%)	0 ( 0.0%)	1 ( 6.2%)
Dizziness	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Headache	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Sciatica	1 ( 6.2%)	0 ( 0.0%)	0 ( 0.0%)
Reproductive system and breast disorders			
Menstrual Discomfort	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Respiratory, thoracic and mediastinal disorders			
Cough	0 ( 0.0%)	1 ( 6.2%)	0 ( 0.0%)
Nasal Congestion	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Sinus Congestion	1 ( 6.2%)	0 ( 0.0%)	0 ( 0.0%)
Throat Irritation	1 ( 6.2%)	0 ( 0.0%)	0 ( 0.0%)
Upper Respiratory Tract Congestion	1 ( 6.2%)	0 ( 0.0%)	0 ( 0.0%)
Skin and subcutaneous tissue disorders			
Erythema	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Pruritus	1 ( 6.2%)	2 ( 12.5%)	0 ( 0.0%)
Skin Discomfort	0 ( 0.0%)	1 ( 6.2%)	0 ( 0.0%)
Surgical and medical procedures			
Cholecystectomy	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Skin Lesion Excision	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

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