

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 | | | |
| 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%) |
| Cheilitis | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Infections and infestations | | | |
| 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%) |
| 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%) |
| Wound Infection | 0 (0.0%) | 1 (3.3%) | 0 (0.0%) |
| Paronychia | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Sinusitis | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Urinary Tract Infection | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Bronchitis | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Nail Infection | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Tinea Pedis | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Injury, poisoning and procedural complications | | | |
| Heat Cramps | 1 (3.3%) | 0 (0.0%) | 0 (0.0%) |
| Procedural Pain | 0 (0.0%) | 1 (3.3%) | 0 (0.0%) |
| Fall | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Muscle Injury | 0 (0.0%) | 0 (0.0%) | 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%) |

Table 1.0
Adverse Events by Severity
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| 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 | | | |
| 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%) |
| Cheilitis | 0 (0.0%) | 1 (5.3%) | 0 (0.0%) |
| Infections and infestations | | | |
| 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%) |
| 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%) |
| Wound Infection | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Paronychia | 0 (0.0%) | 1 (5.3%) | 0 (0.0%) |
| Sinusitis | 1 (5.3%) | 0 (0.0%) | 0 (0.0%) |
| Urinary Tract Infection | 0 (0.0%) | 2 (10.5%) | 0 (0.0%) |
| Bronchitis | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Nail Infection | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Tinea Pedis | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Injury, poisoning and procedural complications | | | |
| Heat Cramps | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Procedural Pain | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Fall | 1 (5.3%) | 0 (0.0%) | 0 (0.0%) |
| Muscle Injury | 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%) |

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 | | | |
| 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%) |
| Cheilitis | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Infections and infestations | | | |
| 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%) |
| 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%) |
| Wound Infection | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Paronychia | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Sinusitis | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Urinary Tract Infection | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Bronchitis | 0 (0.0%) | 2 (20.0%) | 0 (0.0%) |
| Nail Infection | 0 (0.0%) | 1 (10.0%) | 0 (0.0%) |
| Tinea Pedis | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Injury, poisoning and procedural complications | | | |
| Heat Cramps | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Procedural Pain | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Fall | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Muscle Injury | 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%) |

Table 1.0
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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 | | | |
| 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%) |
| Cheilitis | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Infections and infestations | | | |
| 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%) |
| 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%) |
| Wound Infection | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Paronychia | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Sinusitis | 0 (0.0%) | 1 (6.2%) | 0 (0.0%) |
| Urinary Tract Infection | 0 (0.0%) | 1 (6.2%) | 0 (0.0%) |
| Bronchitis | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Nail Infection | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Tinea Pedis | 0 (0.0%) | 1 (6.2%) | 0 (0.0%) |
| Injury, poisoning and procedural complications | | | |
| Heat Cramps | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Procedural Pain | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Fall | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Muscle Injury | 0 (0.0%) | 1 (6.2%) | 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%) |

Table 1.0
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| System Organ Class Preferred Term | ARM A (N=30) | | |
|--|-----------------|-----------|-----------|
| | Mild | Mod** | Severe |
| Vitamin D Decreased | 1 (3.3%) | 0 (0.0%) | 0 (0.0%) |
| Musculoskeletal and connective tissue disorders | | | |
| 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%) |
| Back Pain | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Nervous system disorders | | | |
| Dizziness | 1 (3.3%) | 0 (0.0%) | 0 (0.0%) |
| Headache | 10 (33.3%) | 1 (3.3%) | 0 (0.0%) |
| Burning Sensation | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Sciatica | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Respiratory, thoracic and mediastinal disorders | | | |
| Nasal Congestion | 1 (3.3%) | 0 (0.0%) | 0 (0.0%) |
| Cough | 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%) |
| 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%) |
| Skin and subcutaneous tissue disorders | | | |
| Erythema | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Skin Discomfort | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Pruritus | 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 |
| Vitamin D Decreased | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Musculoskeletal and connective tissue disorders | | | |
| 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%) |
| Back Pain | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Nervous system disorders | | | |
| Dizziness | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Headache | 1 (5.3%) | 1 (5.3%) | 0 (0.0%) |
| Burning Sensation | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Sciatica | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Respiratory, thoracic and mediastinal disorders | | | |
| Nasal Congestion | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Cough | 0 (0.0%) | 1 (5.3%) | 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%) |
| 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%) |
| Skin and subcutaneous tissue disorders | | | |
| Erythema | 2 (10.5%) | 0 (0.0%) | 0 (0.0%) |
| Skin Discomfort | 1 (5.3%) | 0 (0.0%) | 0 (0.0%) |
| Pruritus | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |

Table 1.0
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Safety Population

| System Organ Class Preferred Term | ARM C (N=10) | | |
|--|-----------------|------------|-----------|
| | Mild | Mod** | Severe |
| Vitamin D Decreased | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Musculoskeletal and connective tissue disorders | | | |
| 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%) |
| Back Pain | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Nervous system disorders | | | |
| Dizziness | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Headache | 0 (0.0%) | 1 (10.0%) | 0 (0.0%) |
| Burning Sensation | 1 (10.0%) | 0 (0.0%) | 0 (0.0%) |
| Sciatica | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Respiratory, thoracic and mediastinal disorders | | | |
| Nasal Congestion | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Cough | 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%) |
| 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%) |
| Skin and subcutaneous tissue disorders | | | |
| Erythema | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Skin Discomfort | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Pruritus | 0 (0.0%) | 1 (10.0%) | 0 (0.0%) |

Table 1.0
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Safety Population

| System Organ Class Preferred Term | ARM D (N=16) | | |
|--|-----------------|------------|-----------|
| | Mild | Mod** | Severe |
| Vitamin D Decreased | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Musculoskeletal and connective tissue disorders | | | |
| 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%) |
| Back Pain | 1 (6.2%) | 0 (0.0%) | 0 (0.0%) |
| Nervous system disorders | | | |
| Dizziness | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Headache | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Burning Sensation | 0 (0.0%) | 0 (0.0%) | 1 (6.2%) |
| Sciatica | 1 (6.2%) | 0 (0.0%) | 0 (0.0%) |
| Respiratory, thoracic and mediastinal disorders | | | |
| Nasal Congestion | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Cough | 0 (0.0%) | 1 (6.2%) | 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%) |
| 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%) |
| Skin and subcutaneous tissue disorders | | | |
| Erythema | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Skin Discomfort | 0 (0.0%) | 1 (6.2%) | 0 (0.0%) |
| Pruritus | 1 (6.2%) | 2 (12.5%) | 0 (0.0%) |

Table 1.0
Adverse Events by Severity
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| System Organ Class Preferred Term | ARM A (N=30) | | |
|--|-----------------|-----------|-----------|
| | Mild | Mod** | Severe |
| ----- | | | |
| 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%) |
| Reproductive system and breast disorders | | | |
| Menstrual Discomfort | 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 |
| ----- | | | |
| 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%) |
| Reproductive system and breast disorders | | | |
| Menstrual Discomfort | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |

Table 1.0
Adverse Events by Severity
Safety Population

| System Organ Class Preferred Term | ARM C (N=10) | | |
|--|-----------------|------------|-----------|
| | Mild | Mod** | Severe |
| ----- | | | |
| 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%) |
| Reproductive system and breast disorders | | | |
| Menstrual Discomfort | 0 (0.0%) | 1 (10.0%) | 0 (0.0%) |

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| System Organ Class Preferred Term | ARM D (N=16) | | |
|--|-----------------|-----------|-----------|
| | Mild | Mod** | Severe |
| ----- | | | |
| 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%) |
| Reproductive system and breast disorders | | | |
| Menstrual Discomfort | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |