

Table 1.0  
Adverse Events by Severity  
Safety Population

| System Organ Class<br>Preferred Term                 | ARM A<br>(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<br>Preferred Term                 | ARM B<br>(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  
Safety Population

| System Organ Class<br>Preferred Term                 | ARM C<br>(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  
Safety Population

| System Organ Class<br>Preferred Term                 | ARM D<br>(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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| System Organ Class<br>Preferred Term            | ARM A<br>(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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| System Organ Class<br>Preferred Term            | ARM B<br>(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%) |
| Nervous system disorders                        |                 |            |           |

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Safety Population

| System Organ Class<br>Preferred Term            | ARM C<br>(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%) |
| Nervous system disorders                        |                 |           |           |

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Adverse Events by Severity  
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| System Organ Class<br>Preferred Term            | ARM D<br>(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%) |
| Nervous system disorders                        |                 |           |           |

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| System Organ Class<br>Preferred Term            | ARM A<br>(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<br>Preferred Term            | ARM B<br>(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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| System Organ Class<br>Preferred Term            | ARM C<br>(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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| System Organ Class<br>Preferred Term            | ARM D<br>(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%) |

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