

| System Organ Class                                   | CTC term                    | Number of patients with the AE a least once in Arm A | Percentage of no. of patients in arm A (N= 21) | Number of total occurrence of the AE in Arm A | Number of patients with the AE a least once in Arm B | Percentage of no. of patients in arm B (N= 19) | Number of total occurrence of the AE in Arm B |
|--|-----------------------------|--|--|---|--|--|---|
| Blood and lymphatic system disorders                 | Anemia                      | 8  | 38.10%   | 13  | 1  | 5.26%  | 3   |
| Ear and labyrinth disorders                          | Vertigo                     | 2  | 9.52%  | 2   | 0  | 0.00%  | 0   |
| Endocrine disorders                                  | Adrenal insufficiency       | 2  | 9.52%  | 2   | 0  | 0.00%  | 0   |
| Endocrine disorders                                  | Cushingoid                  | 0  | 0.00%  | 0   | 1  | 5.26%  | 1   |
| Endocrine disorders                                  | Hyperthyroidism             | 4  | 19.05%   | 5   | 4  | 21.05%   | 4   |
| Endocrine disorders                                  | Hypothyroidism              | 1  | 4.76%  | 1   | 3  | 15.79%   | 3   |
| Eye disorders  | Eye pain                    | 0  | 0.00%  | 0   | 1  | 5.26%  | 1   |
| Gastrointestinal disorders                           | Abdominal pain              | 1  | 4.76%  | 1   | 1  | 5.26%  | 3   |
| Gastrointestinal disorders                           | Ascites                     | 1  | 4.76%  | 3   | 2  | 10.53%   | 2   |
| Gastrointestinal disorders                           | Colitis                     | 3  | 14.29%   | 3   | 1  | 5.26%  | 1   |
| Gastrointestinal disorders                           | Constipation                | 0  | 0.00%  | 0   | 1  | 5.26%  | 1   |
| Gastrointestinal disorders                           | Diarrhea                    | 11   | 52.38%   | 14  | 5  | 26.32%   | 5   |
| Gastrointestinal disorders                           | Dry mouth                   | 4  | 19.05%   | 4   | 0  | 0.00%  | 0   |
| Gastrointestinal disorders                           | Dyspepsia                   | 0  | 0.00%  | 0   | 1  | 5.26%  | 1   |
| Gastrointestinal disorders                           | Dysphagia                   | 1  | 4.76%  | 1   | 1  | 5.26%  | 1   |
| Gastrointestinal disorders                           | Flatulence                  | 0  | 0.00%  | 0   | 1  | 5.26%  | 1   |
| Gastrointestinal disorders                           | Gastritis                   | 0  | 0.00%  | 0   | 2  | 10.53%   | 2   |
| Gastrointestinal disorders                           | Gastroesophageal reflux dis | 2  | 9.52%  | 2   | 1  | 5.26%  | 1   |
| Gastrointestinal disorders                           | Ileus                       | 0  | 0.00%  | 0   | 1  | 5.26%  | 1   |
| Gastrointestinal disorders                           | Mucositis oral              | 2  | 9.52%  | 2   | 0  | 0.00%  | 0   |
| Gastrointestinal disorders                           | Nausea                      | 10   | 47.62%   | 12  | 4  | 21.05%   | 4   |
| Gastrointestinal disorders                           | Pancreatitis                | 0  | 0.00%  | 0   | 1  | 5.26%  | 1   |
| Gastrointestinal disorders                           | Stomach pain                | 1  | 4.76%  | 1   | 1  | 5.26%  | 1   |
| Gastrointestinal disorders                           | Vomiting                    | 4  | 19.05%   | 5   | 3  | 15.79%   | 3   |
| General disorders and administration site conditions | Chills                      | 3  | 14.29%   | 4   | 0  | 0.00%  | 0   |
| General disorders and administration site conditions | Edema limbs                 | 2  | 9.52%  | 3   | 1  | 5.26%  | 1   |
| General disorders and administration site conditions | Edema trunk                 | 0  | 0.00%  | 0   | 1  | 5.26%  | 1   |
| General disorders and administration site conditions | Fatigue                     | 9  | 42.86%   | 11  | 5  | 26.32%   | 5   |
| General disorders and administration site conditions | Fever                       | 3  | 14.29%   | 3   | 2  | 10.53%   | 5   |
| General disorders and administration site conditions | Flu like symptoms           | 1  | 4.76%  | 2   | 2  | 10.53%   | 3   |
| General disorders and administration site conditions | Localized edema             | 0  | 0.00%  | 0   | 1  | 5.26%  | 1   |
| General disorders and administration site conditions | Malaise                     | 2  | 9.52%  | 2   | 0  | 0.00%  | 0   |
| General disorders and administration site conditions | Pain                        | 2  | 9.52%  | 2   | 2  | 10.53%   | 3   |
| Hepatobiliary disorders                              | Portal vein thrombosis      | 0  | 0.00%  | 0   | 1  | 5.26%  | 1   |
| Infections and infestations                          | Bronchial infection         | 1  | 4.76%  | 1   | 1  | 5.26%  | 1   |
| Infections and infestations                          | Herpes simplex reactivation | 1  | 4.76%  | 1   | 1  | 5.26%  | 2   |
| Infections and infestations                          | Mucosal infection           | 0  | 0.00%  | 0   | 1  | 5.26%  | 1   |
| Infections and infestations                          | Otitis externa              | 0  | 0.00%  | 0   | 1  | 5.26%  | 1   |
| Infections and infestations                          | Skin infection              | 0  | 0.00%  | 0   | 1  | 5.26%  | 1   |
| Infections and infestations                          | Urinary tract infection     | 1  | 4.76%  | 1   | 1  | 5.26%  | 1   |
| Investigations                                       | Alanine aminotransferase in | 4  | 19.05%   | 5   | 5  | 26.32%   | 6   |
| Investigations                                       | Alkaline phosphatase increa | 1  | 4.76%  | 2   | 2  | 10.53%   | 2   |
| Investigations                                       | Aspartate aminotransferase  | 6  | 28.57%   | 8   | 6  | 31.58%   | 6   |
| Investigations                                       | Blood bilirubin increased   | 5  | 23.81%   | 5   | 2  | 10.53%   | 2   |
| Investigations                                       | Blood lactate dehydrogenas  | 2  | 9.52%  | 3   | 1  | 5.26%  | 1   |
| Investigations                                       | GGT increased               | 3  | 14.29%   | 3   | 2  | 10.53%   | 3   |
| Investigations                                       | Lipase increased            | 2  | 9.52%  | 2   | 6  | 31.58%   | 9   |
| Investigations                                       | Neutrophil count decreased  | 4  | 19.05%   | 5   | 0  | 0.00%  | 0   |
| Investigations                                       | Platelet count decreased    | 6  | 28.57%   | 7   | 1  | 5.26%  | 1   |
| Investigations                                       | Serum amylase increased     | 0  | 0.00%  | 0   | 4  | 21.05%   | 4   |
| Investigations                                       | Weight loss                 | 2  | 9.52%  | 2   | 2  | 10.53%   | 2   |
| Investigations                                       | White blood cell decreased  | 3  | 14.29%   | 6   | 2  | 10.53%   | 3   |
| Metabolism and nutrition disorders                   | Anorexia                    | 4  | 19.05%   | 4   | 2  | 10.53%   | 2   |
| Metabolism and nutrition disorders                   | Hyperglycemia               | 3  | 14.29%   | 3   | 0  | 0.00%  | 0   |
| Metabolism and nutrition disorders                   | Hypoalbuminemia             | 1  | 4.76%  | 2   | 1  | 5.26%  | 1   |
| Metabolism and nutrition disorders                   | Hypokalemia                 | 2  | 9.52%  | 2   | 3  | 15.79%   | 3   |
| Metabolism and nutrition disorders                   | Hypomagnesemia              | 0  | 0.00%  | 0   | 1  | 5.26%  | 1   |
| Musculoskeletal and connective tissue disorders      | Arthralgia                  | 0  | 0.00%  | 0   | 2  | 10.53%   | 2   |
| Musculoskeletal and connective tissue disorders      | Arthritis                   | 1  | 4.76%  | 3   | 1  | 5.26%  | 4   |
| Musculoskeletal and connective tissue disorders      | Muscle cramp                | 2  | 9.52%  | 2   | 1  | 5.26%  | 1   |
| Musculoskeletal and connective tissue disorders      | Pain in extremity           | 1  | 4.76%  | 1   | 1  | 5.26%  | 1   |
| Nervous system disorders                             | Dysesthesia                 | 0  | 0.00%  | 0   | 1  | 5.26%  | 1   |
| Nervous system disorders                             | Dysgeusia                   | 2  | 9.52%  | 2   | 1  | 5.26%  | 1   |
| Nervous system disorders                             | Encephalopathy              | 2  | 9.52%  | 2   | 0  | 0.00%  | 0   |
| Nervous system disorders                             | Extrapyramidal disorder     | 0  | 0.00%  | 0   | 1  | 5.26%  | 1   |
| Nervous system disorders                             | Peripheral sensory neuropat | 2  | 9.52%  | 2   | 0  | 0.00%  | 0   |
| Nervous system disorders                             | Somnolence                  | 0  | 0.00%  | 0   | 1  | 5.26%  | 1   |
| Renal and urinary disorders                          | Acute kidney injury         | 0  | 0.00%  | 0   | 1  | 5.26%  | 1   |
| Renal and urinary disorders                          | Hematuria                   | 0  | 0.00%  | 0   | 2  | 10.53%   | 2   |
| Renal and urinary disorders                          | Proteinuria                 | 0  | 0.00%  | 0   | 3  | 15.79%   | 4   |
| Reproductive system and breast disorders             | Testicular disorder         | 0  | 0.00%  | 0   | 1  | 5.26%  | 1   |
| Respiratory, thoracic and mediastinal disorders      | Dyspnea                     | 1  | 4.76%  | 1   | 3  | 15.79%   | 3   |
| Respiratory, thoracic and mediastinal disorders      | Hoarseness                  | 0  | 0.00%  | 0   | 1  | 5.26%  | 1   |
| Respiratory, thoracic and mediastinal disorders      | Hypoxia                     | 0  | 0.00%  | 0   | 1  | 5.26%  | 1   |
| Skin and subcutaneous tissue disorders               | Alopecia                    | 1  | 4.76%  | 1   | 1  | 5.26%  | 1   |
| Skin and subcutaneous tissue disorders               | Dry skin                    | 3  | 14.29%   | 3   | 2  | 10.53%   | 3   |

|  |                            |   |        |   |   |        |   |
|--|----------------------------|---|--------|---|---|--------|---|
| Skin and subcutaneous tissue disorders | Eczema                     | 0 | 0.00%  | 0 | 1 | 5.26%  | 1 |
| Skin and subcutaneous tissue disorders | Hyperhidrosis              | 0 | 0.00%  | 0 | 2 | 10.53% | 2 |
| Skin and subcutaneous tissue disorders | Palmar-plantar erythrodyse | 6 | 28.57% | 9 | 0 | 0.00%  | 0 |
| Skin and subcutaneous tissue disorders | Pruritus                   | 3 | 14.29% | 3 | 4 | 21.05% | 4 |
| Skin and subcutaneous tissue disorders | Rash acneiform             | 2 | 9.52%  | 2 | 1 | 5.26%  | 1 |
| Skin and subcutaneous tissue disorders | Rash maculo-papular        | 1 | 4.76%  | 2 | 3 | 15.79% | 5 |
| Vascular disorders                     | Hypertension               | 3 | 14.29% | 4 | 3 | 15.79% | 7 |
| Vascular disorders                     | Hypotension                | 3 | 14.29% | 3 | 2 | 10.53% | 2 |