| **Summary of TEAEs by SOC by PT Safety Analysis Set** | | | | |
| --- | --- | --- | --- | --- |
| **System Organ Class  Preferred Term** | **Placebo (N = 86 n (%)** | **Low Dose (N = 84 n (%)** | **High Dose (N = 84 n (%)** | **Total (N = 254 n (%)** |
| CARDIAC DISORDERS | 13 (15.1) | 13 (15.5) | 18 (21.4) | 44 (17.3) |
| ATRIAL FIBRILLATION | 1 (1.2) | 1 (1.2) | 3 (3.6) | 5 (2) |
| ATRIAL HYPERTROPHY | 1 (1.2) | 0 | 0 | 1 (0.4) |
| ATRIOVENTRICULAR BLOCK FIRST DEGREE | 1 (1.2) | 1 (1.2) | 0 | 2 (0.8) |
| BRADYCARDIA | 1 (1.2) | 0 | 0 | 1 (0.4) |
| BUNDLE BRANCH BLOCK LEFT | 1 (1.2) | 0 | 0 | 1 (0.4) |
| BUNDLE BRANCH BLOCK RIGHT | 1 (1.2) | 1 (1.2) | 0 | 2 (0.8) |
| CARDIAC FAILURE CONGESTIVE | 1 (1.2) | 0 | 0 | 1 (0.4) |
| SINUS ARRHYTHMIA | 1 (1.2) | 0 | 0 | 1 (0.4) |
| SUPRAVENTRICULAR EXTRASYSTOLES | 1 (1.2) | 1 (1.2) | 1 (1.2) | 3 (1.2) |
| TACHYCARDIA | 1 (1.2) | 0 | 0 | 1 (0.4) |
| VENTRICULAR HYPERTROPHY | 1 (1.2) | 0 | 0 | 1 (0.4) |
| ATRIOVENTRICULAR BLOCK SECOND DEGREE | 2 (2.3) | 0 | 3 (3.6) | 5 (2) |
| SINUS BRADYCARDIA | 2 (2.3) | 7 (8.3) | 8 (9.5) | 17 (6.7) |
| MYOCARDIAL INFARCTION | 4 (4.7) | 2 (2.4) | 4 (4.8) | 10 (3.9) |
| EAR AND LABYRINTH DISORDERS | 1 (1.2) | 2 (2.4) | 1 (1.2) | 4 (1.6) |
| EAR PAIN | 1 (1.2) | 0 | 0 | 1 (0.4) |
| EYE DISORDERS | 4 (4.7) | 2 (2.4) | 1 (1.2) | 7 (2.8) |
| EYE ALLERGY | 1 (1.2) | 0 | 0 | 1 (0.4) |
| EYE PRURITUS | 1 (1.2) | 0 | 0 | 1 (0.4) |
| EYE SWELLING | 1 (1.2) | 0 | 0 | 1 (0.4) |
| GLAUCOMA | 1 (1.2) | 0 | 0 | 1 (0.4) |
| CONJUNCTIVITIS | 2 (2.3) | 0 | 0 | 2 (0.8) |
| GASTROINTESTINAL DISORDERS | 17 (19.8) | 15 (17.9) | 21 (25) | 53 (20.9) |
| ABDOMINAL PAIN | 1 (1.2) | 3 (3.6) | 1 (1.2) | 5 (2) |
| CONSTIPATION | 1 (1.2) | 0 | 0 | 1 (0.4) |
| DYSPEPSIA | 1 (1.2) | 1 (1.2) | 1 (1.2) | 3 (1.2) |
| FLATULENCE | 1 (1.2) | 0 | 0 | 1 (0.4) |
| GASTROOESOPHAGEAL REFLUX DISEASE | 1 (1.2) | 0 | 0 | 1 (0.4) |
| GLOSSITIS | 1 (1.2) | 0 | 0 | 1 (0.4) |
| HIATUS HERNIA | 1 (1.2) | 0 | 0 | 1 (0.4) |
| NAUSEA | 3 (3.5) | 3 (3.6) | 6 (7.1) | 12 (4.7) |
| VOMITING | 3 (3.5) | 3 (3.6) | 7 (8.3) | 13 (5.1) |
| DIARRHOEA | 9 (10.5) | 5 (6) | 4 (4.8) | 18 (7.1) |
| GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS | 21 (24.4) | 47 (56) | 40 (47.6) | 108 (42.5) |
| APPLICATION SITE INDURATION | 1 (1.2) | 0 | 0 | 1 (0.4) |
| APPLICATION SITE REACTION | 1 (1.2) | 0 | 1 (1.2) | 2 (0.8) |
| APPLICATION SITE VESICLES | 1 (1.2) | 4 (4.8) | 6 (7.1) | 11 (4.3) |
| ASTHENIA | 1 (1.2) | 0 | 1 (1.2) | 2 (0.8) |
| CHILLS | 1 (1.2) | 1 (1.2) | 1 (1.2) | 3 (1.2) |
| FATIGUE | 1 (1.2) | 5 (6) | 5 (6) | 11 (4.3) |
| OEDEMA PERIPHERAL | 2 (2.3) | 1 (1.2) | 2 (2.4) | 5 (2) |
| PYREXIA | 2 (2.3) | 0 | 1 (1.2) | 3 (1.2) |
| APPLICATION SITE ERYTHEMA | 3 (3.5) | 12 (14.3) | 15 (17.9) | 30 (11.8) |
| APPLICATION SITE IRRITATION | 3 (3.5) | 9 (10.7) | 9 (10.7) | 21 (8.3) |
| APPLICATION SITE DERMATITIS | 5 (5.8) | 9 (10.7) | 7 (8.3) | 21 (8.3) |
| APPLICATION SITE PRURITUS | 6 (7) | 22 (26.2) | 22 (26.2) | 50 (19.7) |
| HEPATOBILIARY DISORDERS | 1 (1.2) | 0 | 0 | 1 (0.4) |
| HYPERBILIRUBINAEMIA | 1 (1.2) | 0 | 0 | 1 (0.4) |
| INFECTIONS AND INFESTATIONS | 16 (18.6) | 10 (11.9) | 13 (15.5) | 39 (15.4) |
| BRONCHITIS | 1 (1.2) | 0 | 0 | 1 (0.4) |
| CERVICITIS | 1 (1.2) | 0 | 0 | 1 (0.4) |
| CYSTITIS | 1 (1.2) | 0 | 1 (1.2) | 2 (0.8) |
| GASTROENTERITIS VIRAL | 1 (1.2) | 0 | 0 | 1 (0.4) |
| INFLUENZA | 1 (1.2) | 1 (1.2) | 1 (1.2) | 3 (1.2) |
| LOCALISED INFECTION | 1 (1.2) | 1 (1.2) | 0 | 2 (0.8) |
| VAGINAL MYCOSIS | 1 (1.2) | 0 | 0 | 1 (0.4) |
| EAR INFECTION | 2 (2.3) | 0 | 0 | 2 (0.8) |
| NASOPHARYNGITIS | 2 (2.3) | 4 (4.8) | 6 (7.1) | 12 (4.7) |
| URINARY TRACT INFECTION | 2 (2.3) | 0 | 1 (1.2) | 3 (1.2) |
| UPPER RESPIRATORY TRACT INFECTION | 6 (7) | 1 (1.2) | 3 (3.6) | 10 (3.9) |
| INJURY, POISONING AND PROCEDURAL COMPLICATIONS | 4 (4.7) | 5 (6) | 5 (6) | 14 (5.5) |
| CONTUSION | 1 (1.2) | 1 (1.2) | 2 (2.4) | 4 (1.6) |
| FALL | 1 (1.2) | 2 (2.4) | 1 (1.2) | 4 (1.6) |
| HIP FRACTURE | 1 (1.2) | 0 | 2 (2.4) | 3 (1.2) |
| SKIN LACERATION | 1 (1.2) | 2 (2.4) | 0 | 3 (1.2) |
| EXCORIATION | 2 (2.3) | 1 (1.2) | 1 (1.2) | 4 (1.6) |
| INVESTIGATIONS | 10 (11.6) | 7 (8.3) | 6 (7.1) | 23 (9.1) |
| BLOOD ALKALINE PHOSPHATASE INCREASED | 1 (1.2) | 0 | 0 | 1 (0.4) |
| BLOOD CREATINE PHOSPHOKINASE INCREASED | 1 (1.2) | 0 | 0 | 1 (0.4) |
| BLOOD URINE PRESENT | 1 (1.2) | 0 | 0 | 1 (0.4) |
| CYSTOSCOPY | 1 (1.2) | 0 | 0 | 1 (0.4) |
| ELECTROCARDIOGRAM T WAVE AMPLITUDE DECREASED | 1 (1.2) | 1 (1.2) | 0 | 2 (0.8) |
| HEART RATE INCREASED | 1 (1.2) | 0 | 0 | 1 (0.4) |
| HEART RATE IRREGULAR | 1 (1.2) | 0 | 0 | 1 (0.4) |
| ELECTROCARDIOGRAM T WAVE INVERSION | 2 (2.3) | 1 (1.2) | 1 (1.2) | 4 (1.6) |
| ELECTROCARDIOGRAM ST SEGMENT DEPRESSION | 4 (4.7) | 1 (1.2) | 0 | 5 (2) |
| METABOLISM AND NUTRITION DISORDERS | 6 (7) | 1 (1.2) | 3 (3.6) | 10 (3.9) |
| DECREASED APPETITE | 1 (1.2) | 0 | 1 (1.2) | 2 (0.8) |
| DEHYDRATION | 1 (1.2) | 0 | 0 | 1 (0.4) |
| DIABETES MELLITUS | 1 (1.2) | 0 | 0 | 1 (0.4) |
| FOOD CRAVING | 1 (1.2) | 1 (1.2) | 0 | 2 (0.8) |
| HYPONATRAEMIA | 1 (1.2) | 0 | 0 | 1 (0.4) |
| INCREASED APPETITE | 1 (1.2) | 0 | 1 (1.2) | 2 (0.8) |
| MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS | 5 (5.8) | 7 (8.3) | 8 (9.5) | 20 (7.9) |
| ARTHRALGIA | 1 (1.2) | 2 (2.4) | 1 (1.2) | 4 (1.6) |
| ARTHRITIS | 1 (1.2) | 0 | 1 (1.2) | 2 (0.8) |
| BACK PAIN | 1 (1.2) | 1 (1.2) | 3 (3.6) | 5 (2) |
| PAIN IN EXTREMITY | 1 (1.2) | 0 | 0 | 1 (0.4) |
| SHOULDER PAIN | 1 (1.2) | 2 (2.4) | 0 | 3 (1.2) |
| NERVOUS SYSTEM DISORDERS | 12 (14) | 20 (23.8) | 27 (32.1) | 59 (23.2) |
| PARKINSON'S DISEASE | 1 (1.2) | 0 | 0 | 1 (0.4) |
| PSYCHOMOTOR HYPERACTIVITY | 1 (1.2) | 0 | 0 | 1 (0.4) |
| DIZZINESS | 2 (2.3) | 8 (9.5) | 12 (14.3) | 22 (8.7) |
| SOMNOLENCE | 2 (2.3) | 3 (3.6) | 1 (1.2) | 6 (2.4) |
| HEADACHE | 7 (8.1) | 3 (3.6) | 6 (7.1) | 16 (6.3) |
| PSYCHIATRIC DISORDERS | 10 (11.6) | 10 (11.9) | 9 (10.7) | 29 (11.4) |
| ANXIETY | 1 (1.2) | 3 (3.6) | 0 | 4 (1.6) |
| COMPLETED SUICIDE | 1 (1.2) | 0 | 0 | 1 (0.4) |
| DELUSION | 1 (1.2) | 0 | 1 (1.2) | 2 (0.8) |
| DISORIENTATION | 1 (1.2) | 0 | 0 | 1 (0.4) |
| IRRITABILITY | 1 (1.2) | 1 (1.2) | 0 | 2 (0.8) |
| AGITATION | 2 (2.3) | 2 (2.4) | 1 (1.2) | 5 (2) |
| CONFUSIONAL STATE | 2 (2.3) | 3 (3.6) | 1 (1.2) | 6 (2.4) |
| INSOMNIA | 2 (2.3) | 0 | 2 (2.4) | 4 (1.6) |
| RENAL AND URINARY DISORDERS | 4 (4.7) | 4 (4.8) | 3 (3.6) | 11 (4.3) |
| DYSURIA | 1 (1.2) | 1 (1.2) | 0 | 2 (0.8) |
| MICTURITION URGENCY | 1 (1.2) | 1 (1.2) | 1 (1.2) | 3 (1.2) |
| NEPHROLITHIASIS | 1 (1.2) | 0 | 1 (1.2) | 2 (0.8) |
| POLLAKIURIA | 1 (1.2) | 0 | 0 | 1 (0.4) |
| REPRODUCTIVE SYSTEM AND BREAST DISORDERS | 2 (2.3) | 0 | 1 (1.2) | 3 (1.2) |
| BENIGN PROSTATIC HYPERPLASIA | 1 (1.2) | 0 | 1 (1.2) | 2 (0.8) |
| PELVIC PAIN | 1 (1.2) | 0 | 0 | 1 (0.4) |
| RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS | 10 (11.6) | 10 (11.9) | 10 (11.9) | 30 (11.8) |
| DYSPNOEA | 1 (1.2) | 1 (1.2) | 1 (1.2) | 3 (1.2) |
| EMPHYSEMA | 1 (1.2) | 0 | 0 | 1 (0.4) |
| HAEMOPTYSIS | 1 (1.2) | 0 | 0 | 1 (0.4) |
| POSTNASAL DRIP | 1 (1.2) | 0 | 0 | 1 (0.4) |
| RALES | 1 (1.2) | 0 | 0 | 1 (0.4) |
| COUGH | 3 (3.5) | 6 (7.1) | 5 (6) | 14 (5.5) |
| NASAL CONGESTION | 3 (3.5) | 1 (1.2) | 3 (3.6) | 7 (2.8) |
| SKIN AND SUBCUTANEOUS TISSUE DISORDERS | 21 (24.4) | 42 (50) | 42 (50) | 105 (41.3) |
| ALOPECIA | 1 (1.2) | 0 | 0 | 1 (0.4) |
| COLD SWEAT | 1 (1.2) | 0 | 0 | 1 (0.4) |
| DERMATITIS ATOPIC | 1 (1.2) | 0 | 0 | 1 (0.4) |
| DRUG ERUPTION | 1 (1.2) | 0 | 0 | 1 (0.4) |
| SKIN ULCER | 1 (1.2) | 0 | 0 | 1 (0.4) |
| HYPERHIDROSIS | 2 (2.3) | 4 (4.8) | 8 (9.5) | 14 (5.5) |
| SKIN IRRITATION | 3 (3.5) | 6 (7.1) | 5 (6) | 14 (5.5) |
| RASH | 5 (5.8) | 13 (15.5) | 11 (13.1) | 29 (11.4) |
| PRURITUS | 8 (9.3) | 23 (27.4) | 26 (31) | 57 (22.4) |
| ERYTHEMA | 9 (10.5) | 15 (17.9) | 14 (16.7) | 38 (15) |
| SURGICAL AND MEDICAL PROCEDURES | 2 (2.3) | 1 (1.2) | 2 (2.4) | 5 (2) |
| CATARACT OPERATION | 1 (1.2) | 1 (1.2) | 0 | 2 (0.8) |
| EYE LASER SURGERY | 1 (1.2) | 0 | 0 | 1 (0.4) |
| VASCULAR DISORDERS | 3 (3.5) | 3 (3.6) | 2 (2.4) | 8 (3.1) |
| HYPERTENSION | 1 (1.2) | 1 (1.2) | 1 (1.2) | 3 (1.2) |
| ORTHOSTATIC HYPOTENSION | 1 (1.2) | 0 | 0 | 1 (0.4) |
| HYPOTENSION | 2 (2.3) | 1 (1.2) | 0 | 3 (1.2) |
| CARDIAC DISORDER | 0 | 0 | 1 (1.2) | 1 (0.4) |
| SUPRAVENTRICULAR TACHYCARDIA | 0 | 1 (1.2) | 0 | 1 (0.4) |
| WOLFF-PARKINSON-WHITE SYNDROME | 0 | 1 (1.2) | 0 | 1 (0.4) |
| ATRIAL FLUTTER | 0 | 1 (1.2) | 1 (1.2) | 2 (0.8) |
| PALPITATIONS | 0 | 2 (2.4) | 0 | 2 (0.8) |
| VENTRICULAR EXTRASYSTOLES | 0 | 2 (2.4) | 1 (1.2) | 3 (1.2) |
| CONGENITAL, FAMILIAL AND GENETIC DISORDERS | 0 | 1 (1.2) | 2 (2.4) | 3 (1.2) |
| VENTRICULAR SEPTAL DEFECT | 0 | 1 (1.2) | 2 (2.4) | 3 (1.2) |
| CERUMEN IMPACTION | 0 | 1 (1.2) | 0 | 1 (0.4) |
| TINNITUS | 0 | 1 (1.2) | 0 | 1 (0.4) |
| VERTIGO | 0 | 1 (1.2) | 1 (1.2) | 2 (0.8) |
| CONJUNCTIVAL HAEMORRHAGE | 0 | 1 (1.2) | 0 | 1 (0.4) |
| VISION BLURRED | 0 | 1 (1.2) | 1 (1.2) | 2 (0.8) |
| ABDOMINAL DISCOMFORT | 0 | 0 | 1 (1.2) | 1 (0.4) |
| DYSPHAGIA | 0 | 1 (1.2) | 0 | 1 (0.4) |
| GASTROINTESTINAL HAEMORRHAGE | 0 | 0 | 1 (1.2) | 1 (0.4) |
| RECTAL HAEMORRHAGE | 0 | 1 (1.2) | 0 | 1 (0.4) |
| STOMACH DISCOMFORT | 0 | 0 | 1 (1.2) | 1 (0.4) |
| SALIVARY HYPERSECRETION | 0 | 0 | 4 (4.8) | 4 (1.6) |
| APPLICATION SITE BLEEDING | 0 | 1 (1.2) | 0 | 1 (0.4) |
| APPLICATION SITE DESQUAMATION | 0 | 1 (1.2) | 0 | 1 (0.4) |
| APPLICATION SITE DISCHARGE | 0 | 0 | 1 (1.2) | 1 (0.4) |
| APPLICATION SITE DISCOLOURATION | 0 | 1 (1.2) | 0 | 1 (0.4) |
| APPLICATION SITE WARMTH | 0 | 1 (1.2) | 0 | 1 (0.4) |
| CYST | 0 | 1 (1.2) | 0 | 1 (0.4) |
| FEELING ABNORMAL | 0 | 0 | 1 (1.2) | 1 (0.4) |
| FEELING COLD | 0 | 0 | 1 (1.2) | 1 (0.4) |
| INFLAMMATION | 0 | 1 (1.2) | 0 | 1 (0.4) |
| SECRETION DISCHARGE | 0 | 1 (1.2) | 0 | 1 (0.4) |
| SUDDEN DEATH | 0 | 1 (1.2) | 0 | 1 (0.4) |
| SWELLING | 0 | 1 (1.2) | 0 | 1 (0.4) |
| ULCER | 0 | 1 (1.2) | 0 | 1 (0.4) |
| APPLICATION SITE PAIN | 0 | 0 | 2 (2.4) | 2 (0.8) |
| APPLICATION SITE PERSPIRATION | 0 | 0 | 2 (2.4) | 2 (0.8) |
| CHEST DISCOMFORT | 0 | 0 | 2 (2.4) | 2 (0.8) |
| CHEST PAIN | 0 | 0 | 2 (2.4) | 2 (0.8) |
| OEDEMA | 0 | 2 (2.4) | 0 | 2 (0.8) |
| PAIN | 0 | 1 (1.2) | 1 (1.2) | 2 (0.8) |
| APPLICATION SITE SWELLING | 0 | 1 (1.2) | 2 (2.4) | 3 (1.2) |
| APPLICATION SITE URTICARIA | 0 | 2 (2.4) | 1 (1.2) | 3 (1.2) |
| MALAISE | 0 | 1 (1.2) | 2 (2.4) | 3 (1.2) |
| IMMUNE SYSTEM DISORDERS | 0 | 1 (1.2) | 1 (1.2) | 2 (0.8) |
| HYPERSENSITIVITY | 0 | 1 (1.2) | 0 | 1 (0.4) |
| SEASONAL ALLERGY | 0 | 0 | 1 (1.2) | 1 (0.4) |
| CELLULITIS | 0 | 1 (1.2) | 0 | 1 (0.4) |
| HORDEOLUM | 0 | 0 | 1 (1.2) | 1 (0.4) |
| LOWER RESPIRATORY TRACT INFECTION | 0 | 0 | 1 (1.2) | 1 (0.4) |
| ONYCHOMYCOSIS | 0 | 1 (1.2) | 0 | 1 (0.4) |
| PNEUMONIA | 0 | 1 (1.2) | 0 | 1 (0.4) |
| RHINITIS | 0 | 0 | 1 (1.2) | 1 (0.4) |
| VIRAL INFECTION | 0 | 1 (1.2) | 0 | 1 (0.4) |
| FACIAL BONES FRACTURE | 0 | 0 | 1 (1.2) | 1 (0.4) |
| JOINT DISLOCATION | 0 | 1 (1.2) | 0 | 1 (0.4) |
| WOUND | 0 | 1 (1.2) | 0 | 1 (0.4) |
| BIOPSY | 0 | 0 | 1 (1.2) | 1 (0.4) |
| BIOPSY PROSTATE | 0 | 0 | 1 (1.2) | 1 (0.4) |
| BLOOD CHOLESTEROL INCREASED | 0 | 0 | 1 (1.2) | 1 (0.4) |
| BODY TEMPERATURE INCREASED | 0 | 1 (1.2) | 0 | 1 (0.4) |
| NASAL MUCOSA BIOPSY | 0 | 1 (1.2) | 0 | 1 (0.4) |
| NEUTROPHIL COUNT INCREASED | 0 | 1 (1.2) | 0 | 1 (0.4) |
| URINE ANALYSIS ABNORMAL | 0 | 1 (1.2) | 0 | 1 (0.4) |
| WEIGHT DECREASED | 0 | 0 | 1 (1.2) | 1 (0.4) |
| WHITE BLOOD CELL COUNT INCREASED | 0 | 1 (1.2) | 0 | 1 (0.4) |
| BLOOD GLUCOSE INCREASED | 0 | 1 (1.2) | 1 (1.2) | 2 (0.8) |
| HYPERCHOLESTEROLAEMIA | 0 | 0 | 1 (1.2) | 1 (0.4) |
| MUSCULAR WEAKNESS | 0 | 1 (1.2) | 0 | 1 (0.4) |
| MYALGIA | 0 | 0 | 1 (1.2) | 1 (0.4) |
| FLANK PAIN | 0 | 0 | 2 (2.4) | 2 (0.8) |
| MUSCLE SPASMS | 0 | 1 (1.2) | 1 (1.2) | 2 (0.8) |
| NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS) | 0 | 2 (2.4) | 1 (1.2) | 3 (1.2) |
| COLON CANCER | 0 | 1 (1.2) | 0 | 1 (0.4) |
| MALIGNANT FIBROUS HISTIOCYTOMA | 0 | 1 (1.2) | 0 | 1 (0.4) |
| PROSTATE CANCER | 0 | 0 | 1 (1.2) | 1 (0.4) |
| AMNESIA | 0 | 0 | 1 (1.2) | 1 (0.4) |
| BALANCE DISORDER | 0 | 1 (1.2) | 0 | 1 (0.4) |
| COGNITIVE DISORDER | 0 | 0 | 1 (1.2) | 1 (0.4) |
| COMPLEX PARTIAL SEIZURES | 0 | 1 (1.2) | 0 | 1 (0.4) |
| COORDINATION ABNORMAL | 0 | 1 (1.2) | 0 | 1 (0.4) |
| HEMIANOPIA HOMONYMOUS | 0 | 1 (1.2) | 0 | 1 (0.4) |
| HYPERSOMNIA | 0 | 0 | 1 (1.2) | 1 (0.4) |
| PARAESTHESIA | 0 | 0 | 1 (1.2) | 1 (0.4) |
| PARAESTHESIA ORAL | 0 | 1 (1.2) | 0 | 1 (0.4) |
| PAROSMIA | 0 | 0 | 1 (1.2) | 1 (0.4) |
| PARTIAL SEIZURES WITH SECONDARY GENERALISATION | 0 | 0 | 1 (1.2) | 1 (0.4) |
| STUPOR | 0 | 1 (1.2) | 0 | 1 (0.4) |
| SYNCOPE VASOVAGAL | 0 | 0 | 1 (1.2) | 1 (0.4) |
| BURNING SENSATION | 0 | 0 | 2 (2.4) | 2 (0.8) |
| LETHARGY | 0 | 1 (1.2) | 1 (1.2) | 2 (0.8) |
| TRANSIENT ISCHAEMIC ATTACK | 0 | 2 (2.4) | 1 (1.2) | 3 (1.2) |
| SYNCOPE | 0 | 4 (4.8) | 3 (3.6) | 7 (2.8) |
| DELIRIUM | 0 | 0 | 1 (1.2) | 1 (0.4) |
| HALLUCINATION | 0 | 0 | 1 (1.2) | 1 (0.4) |
| HALLUCINATION, VISUAL | 0 | 0 | 1 (1.2) | 1 (0.4) |
| LIBIDO DECREASED | 0 | 0 | 1 (1.2) | 1 (0.4) |
| LISTLESS | 0 | 0 | 1 (1.2) | 1 (0.4) |
| NIGHTMARE | 0 | 0 | 1 (1.2) | 1 (0.4) |
| RESTLESSNESS | 0 | 1 (1.2) | 0 | 1 (0.4) |
| DEPRESSED MOOD | 0 | 1 (1.2) | 1 (1.2) | 2 (0.8) |
| CALCULUS URETHRAL | 0 | 0 | 1 (1.2) | 1 (0.4) |
| ENURESIS | 0 | 1 (1.2) | 0 | 1 (0.4) |
| INCONTINENCE | 0 | 1 (1.2) | 0 | 1 (0.4) |
| ALLERGIC GRANULOMATOUS ANGIITIS | 0 | 0 | 1 (1.2) | 1 (0.4) |
| DYSPHONIA | 0 | 1 (1.2) | 0 | 1 (0.4) |
| PHARYNGEAL ERYTHEMA | 0 | 0 | 1 (1.2) | 1 (0.4) |
| PRODUCTIVE COUGH | 0 | 0 | 1 (1.2) | 1 (0.4) |
| RESPIRATORY TRACT CONGESTION | 0 | 0 | 1 (1.2) | 1 (0.4) |
| PHARYNGOLARYNGEAL PAIN | 0 | 1 (1.2) | 1 (1.2) | 2 (0.8) |
| RHINORRHOEA | 0 | 1 (1.2) | 1 (1.2) | 2 (0.8) |
| EPISTAXIS | 0 | 1 (1.2) | 2 (2.4) | 3 (1.2) |
| ACTINIC KERATOSIS | 0 | 0 | 1 (1.2) | 1 (0.4) |
| DERMATITIS CONTACT | 0 | 1 (1.2) | 0 | 1 (0.4) |
| RASH MACULO-PAPULAR | 0 | 0 | 1 (1.2) | 1 (0.4) |
| RASH PAPULAR | 0 | 0 | 1 (1.2) | 1 (0.4) |
| SKIN EXFOLIATION | 0 | 1 (1.2) | 0 | 1 (0.4) |
| SKIN ODOUR ABNORMAL | 0 | 0 | 1 (1.2) | 1 (0.4) |
| PRURITUS GENERALISED | 0 | 1 (1.2) | 1 (1.2) | 2 (0.8) |
| RASH ERYTHEMATOUS | 0 | 2 (2.4) | 0 | 2 (0.8) |
| URTICARIA | 0 | 1 (1.2) | 1 (1.2) | 2 (0.8) |
| RASH PRURITIC | 0 | 1 (1.2) | 2 (2.4) | 3 (1.2) |
| BLISTER | 0 | 5 (6) | 1 (1.2) | 6 (2.4) |
| SOCIAL CIRCUMSTANCES | 0 | 0 | 1 (1.2) | 1 (0.4) |
| ALCOHOL USE | 0 | 0 | 1 (1.2) | 1 (0.4) |
| ACROCHORDON EXCISION | 0 | 0 | 1 (1.2) | 1 (0.4) |
| SKIN LESION EXCISION | 0 | 0 | 1 (1.2) | 1 (0.4) |
| HOT FLUSH | 0 | 1 (1.2) | 0 | 1 (0.4) |
| WOUND HAEMORRHAGE | 0 | 0 | 1 (1.2) | 1 (0.4) |