| Adverse Events                          | Arm A | Arm B | Arm C |
|---|-------|-------|-------|
| ABDOMINAL PAIN                          | 1     | 2     | 3     |
| AGITATION                               | 2     | 1     | 2     |
| ALOPECIA                                | 1     | 0     | 0     |
| ANXIETY                                 | 2     | 0     | 4     |
| APPLICATION SITE DERMATITIS             | 9     | 12    | 15    |
| APPLICATION SITE ERYTHEMA               | 3     | 23    | 20    |
| APPLICATION SITE INDURATION             | 1     | 0     | 0     |
| APPLICATION SITE IRRITATION             | 7     | 16    | 18    |
| APPLICATION SITE PRURITUS               | 10    | 35    | 33    |
| APPLICATION SITE REACTION               | 2     | 1     | 0     |
| APPLICATION SITE VESICLES               | 2     | 6     | 5     |
| ARTHRALGIA                              | 1     | 1     | 4     |
| ARTHRITIS                               | 2     | 1     | 0     |
| ASTHENIA                                | 2     | 1     | 0     |
| ATRIAL FIBRILLATION                     | 1     | 5     | 1     |
| ATRIAL HYPERTROPHY                      | 2     | 0     | 0     |
| ATRIOVENTRICULAR BLOCK                  | 1     | 0     | 1     |
| FIRST DEGREE                            |       |       |       |
| ATRIOVENTRICULAR BLOCK                  | 2     | 4     | 0     |
| SECOND DEGREE                           |       |       |       |
| BACK PAIN                               | 2     | 4     | 1     |
| BENIGN PROSTATIC                        | 2     | 1     | 0     |
| HYPERPLASIA                             |       |       |       |
| BLOOD ALKALINE<br>PHOSPHATASE INCREASED | 1     | 0     | 0     |
| BLOOD CREATINE                          | 2     | 0     | 0     |
| PHOSPHOKINASE INCREASED                 |       |       |       |
| BLOOD URINE PRESENT                     | 1     | 0     | 0     |
| BRADYCARDIA                             | 4     | 0     | 0     |
| BRONCHITIS                              | 1     | 0     | 0     |
| BUNDLE BRANCH BLOCK LEFT                | 1     | 0     | 0     |
| BUNDLE BRANCH BLOCK RIGHT               | 2     | 0     | 1     |
| CARDIAC FAILURE                         | 1     | 0     | 0     |
| CONGESTIVE                              |       |       |       |
| CATARACT OPERATION                      | 1     | 0     | 1     |

| Adverse Events           | Arm A | Arm B | Arm C |
|--------------------------|-------|-------|-------|
| CERVICITIS               | 2     | 0     | 0     |
| CHILLS                   | 3     | 1     | 2     |
| COLD SWEAT               | 3     | 0     | 0     |
| COMPLETED SUICIDE        | 1     | 0     | 0     |
| CONFUSIONAL STATE        | 2     | 1     | 3     |
| CONJUNCTIVITIS           | 4     | 0     | 0     |
| CONSTIPATION             | 1     | 0     | 0     |
| CONTUSION                | 1     | 3     | 3     |
| COUGH                    | 4     | 7     | 9     |
| CYSTITIS                 | 1     | 1     | 0     |
| CYSTOSCOPY               | 1     | 0     | 0     |
| DECREASED APPETITE       | 2     | 2     | 0     |
| DEHYDRATION              | 1     | 0     | 0     |
| DELUSION                 | 1     | 1     | 0     |
| DERMATITIS ATOPIC        | 1     | 0     | 0     |
| DIABETES MELLITUS        | 1     | 0     | 0     |
| DIARRHOEA                | 10    | 4     | 7     |
| DISORIENTATION           | 1     | 0     | 0     |
| DIZZINESS                | 3     | 18    | 13    |
| DRUG ERUPTION            | 1     | 0     | 0     |
| DYSPEPSIA                | 2     | 1     | 2     |
| DYSPNOEA                 | 1     | 1     | 1     |
| DYSURIA                  | 1     | 0     | 1     |
| EAR INFECTION            | 4     | 0     | 0     |
| EAR PAIN                 | 2     | 0     | 0     |
| ELECTROCARDIOGRAM ST     | 4     | 0     | 2     |
| SEGMENT DEPRESSION       |       |       |       |
| ELECTROCARDIOGRAM T WAVE | 1     | 0     | 1     |
| AMPLITUDE DECREASED      |       |       |       |
| ELECTROCARDIOGRAM T WAVE | 3     | 1     | 1     |
| INVERSION                | 1     | 0     | 0     |
| EMPHYSEMA                | 1     | 0     | 0     |
| ERYTHEMA                 | 13    | 22    | 24    |
| EXCORIATION  EVE ALLERCY | 3     | 1     | 2     |
| EYE ALLERGY              | 1     | 0     | 0     |
| EYE LASER SURGERY        | 1     | 0     | 0     |
| EYE PRURITUS             | 1     | 0     | 0     |
| EYE SWELLING             | 1     | 0     | 0     |

| Adverse Events                      | Arm A | Arm B | Arm C |
|-------------------------------------|-------|-------|-------|
| FALL                                | 2     | 1     | 2     |
| FATIGUE                             | 2     | 5     | 5     |
| FLATULENCE                          | 2     | 0     | 0     |
| FOOD CRAVING                        | 1     | 0     | 1     |
| GASTROENTERITIS VIRAL               | 1     | 0     | 0     |
| GASTROOESOPHAGEAL REFLUX<br>DISEASE | 1     | 0     | 0     |
| GLAUCOMA                            | 1     | 0     | 0     |
| GLOSSITIS                           | 1     | 0     | 0     |
| HAEMOPTYSIS                         | 2     | 0     | 0     |
| HEADACHE                            | 8     | 9     | 4     |
| HEART RATE INCREASED                | 2     | 0     | 0     |
| HEART RATE IRREGULAR                | 4     | 0     | 0     |
| HIATUS HERNIA                       | 2     | 0     | 0     |
| HIP FRACTURE                        | 2     | 2     | 0     |
| HYPERBILIRUBINAEMIA                 | 1     | 0     | 0     |
| HYPERHIDROSIS                       | 2     | 10    | 5     |
| HYPERTENSION                        | 2     | 2     | 1     |
| HYPONATRAEMIA                       | 1     | 0     | 0     |
| HYPOTENSION                         | 3     | 0     | 1     |
| INCREASED APPETITE                  | 2     | 2     | 0     |
| INFLUENZA                           | 2     | 1     | 1     |
| INSOMNIA                            | 3     | 2     | 0     |
| IRRITABILITY                        | 2     | 0     | 1     |
| LOCALISED INFECTION                 | 2     | 0     | 1     |
| MICTURITION URGENCY                 | 1     | 2     | 1     |
| MYOCARDIAL INFARCTION               | 4     | 8     | 4     |
| NASAL CONGESTION                    | 3     | 4     | 1     |
| NASOPHARYNGITIS                     | 4     | 8     | 9     |
| NAUSEA                              | 3     | 13    | 5     |
| NEPHROLITHIASIS                     | 1     | 1     | 0     |
| OEDEMA PERIPHERAL                   | 5     | 3     | 1     |
| ORTHOSTATIC HYPOTENSION             | 2     | 0     | 0     |
| PAIN IN EXTREMITY                   | 1     | 0     | 0     |
| PARKINSON'S DISEASE                 | 1     | 0     | 0     |
| PELVIC PAIN                         | 2     | 0     | 0     |
| POLLAKIURIA                         | 2     | 0     | 0     |
| POSTNASAL DRIP                      | 2     | 0     | 0     |
| PRURITUS                            | 11    | 38    | 35    |

| Adverse Events                     | Arm A | Arm B | Arm C |
|------------------------------------|-------|-------|-------|
| PSYCHOMOTOR                        | 1     | 0     | 0     |
| HYPERACTIVITY                      |       |       |       |
| PYREXIA                            | 2     | 1     | 0     |
| RALES                              | 2     | 0     | 0     |
| RASH                               | 9     | 18    | 18    |
| SHOULDER PAIN                      | 2     | 0     | 2     |
| SINUS ARRHYTHMIA                   | 2     | 0     | 0     |
| SINUS BRADYCARDIA                  | 2     | 12    | 10    |
| SKIN IRRITATION                    | 4     | 8     | 13    |
| SKIN LACERATION                    | 1     | 0     | 2     |
| SKIN ULCER                         | 2     | 0     | 0     |
| SOMNOLENCE                         | 3     | 1     | 5     |
| SUPRAVENTRICULAR                   | 2     | 1     | 2     |
| EXTRASYSTOLES                      |       |       |       |
| TACHYCARDIA                        | 2     | 0     | 0     |
| UPPER RESPIRATORY TRACT            | 12    | 5     | 2     |
| INFECTION                          |       |       |       |
| URINARY TRACT INFECTION            | 4     | 1     | 0     |
| VAGINAL MYCOSIS                    | 2     | 0     | 0     |
| VENTRICULAR HYPERTROPHY            | 1     | 0     | 0     |
| VOMITING                           | 3     | 9     | 4     |
| ABDOMINAL DISCOMFORT               | 0     | 1     | 0     |
| ACROCHORDON EXCISION               | 0     | 1     | 0     |
| ACTINIC KERATOSIS                  | 0     | 1     | 0     |
| ALCOHOL USE                        | 0     | 1     | 0     |
| ALLERGIC GRANULOMATOUS<br>ANGIITIS | 0     | 1     | 0     |
| AMNESIA                            | 0     | 2     | 0     |
| APPLICATION SITE DISCHARGE         | 0     | 1     | 0     |
| APPLICATION SITE PAIN              | 0     | 2     | 0     |
| APPLICATION SITE                   | 0     | 3     | 0     |
| PERSPIRATION                       |       |       |       |
| APPLICATION SITE SWELLING          | 0     | 3     | 1     |
| APPLICATION SITE URTICARIA         | 0     | 1     | 2     |
| ATRIAL FLUTTER                     | 0     | 2     | 1     |
| BIOPSY                             | 0     | 1     | 0     |
| BIOPSY PROSTATE                    | 0     | 1     | 0     |
| BLISTER                            | 0     | 2     | 8     |

| Adverse Events           | Arm A | Arm B | Arm C |
|--------------------------|-------|-------|-------|
| BLOOD CHOLESTEROL        | 0     | 1     | 0     |
| INCREASED                |       |       |       |
| BLOOD GLUCOSE INCREASED  | 0     | 2     | 1     |
| BURNING SENSATION        | 0     | 2     | 0     |
| CALCULUS URETHRAL        | 0     | 1     | 0     |
| CARDIAC DISORDER         | 0     | 1     | 0     |
| CHEST DISCOMFORT         | 0     | 2     | 0     |
| CHEST PAIN               | 0     | 2     | 0     |
| COGNITIVE DISORDER       | 0     | 1     | 0     |
| DELIRIUM                 | 0     | 1     | 0     |
| DEPRESSED MOOD           | 0     | 1     | 2     |
| EPISTAXIS                | 0     | 2     | 1     |
| FACIAL BONES FRACTURE    | 0     | 1     | 0     |
| FEELING ABNORMAL         | 0     | 1     | 0     |
| FEELING COLD             | 0     | 1     | 0     |
| FLANK PAIN               | 0     | 2     | 0     |
| GASTROINTESTINAL         | 0     | 1     | 0     |
| HAEMORRHAGE              |       |       |       |
| HALLUCINATION            | 0     | 1     | 0     |
| HALLUCINATION, VISUAL    | 0     | 1     | 0     |
| HORDEOLUM                | 0     | 1     | 0     |
| HYPERCHOLESTEROLAEMIA    | 0     | 1     | 0     |
| HYPERSOMNIA              | 0     | 1     | 0     |
| LETHARGY                 | 0     | 1     | 1     |
| LIBIDO DECREASED         | 0     | 1     | 0     |
| LISTLESS                 | 0     | 1     | 0     |
| LOWER RESPIRATORY TRACT  | 0     | 2     | 0     |
| INFECTION                |       |       |       |
| MALAISE                  | 0     | 3     | 2     |
| MUSCLE SPASMS            | 0     | 2     | 1     |
| MYALGIA                  | 0     | 1     | 0     |
| NIGHTMARE                | 0     | 1     | 0     |
| PAIN                     | 0     | 1     | 2     |
| PARAESTHESIA             | 0     | 1     | 0     |
| PAROSMIA                 | 0     | 2     | 0     |
| PARTIAL SEIZURES WITH    | 0     | 1     | 0     |
| SECONDARY GENERALISATION |       |       |       |
| PHARYNGEAL ERYTHEMA      | 0     | 2     | 0     |
| PHARYNGOLARYNGEAL PAIN   | 0     | 1     | 1     |
| PRODUCTIVE COUGH         | 0     | 1     | 0     |

| Adverse Events                 | Arm A | Arm B | Arm C |
|--------------------------------|-------|-------|-------|
| PROSTATE CANCER                | 0     | 1     | 0     |
| PRURITUS GENERALISED           | 0     | 1     | 4     |
| RASH MACULO-PAPULAR            | 0     | 3     | 0     |
| RASH PAPULAR                   | 0     | 2     | 0     |
| RASH PRURITIC                  | 0     | 3     | 2     |
| RESPIRATORY TRACT              | 0     | 1     | 0     |
| CONGESTION                     |       |       |       |
| RHINITIS                       | 0     | 1     | 0     |
| RHINORRHOEA                    | 0     | 2     | 2     |
| SALIVARY HYPERSECRETION        | 0     | 5     | 0     |
| SEASONAL ALLERGY               | 0     | 1     | 0     |
| SKIN LESION EXCISION           | 0     | 1     | 0     |
| SKIN ODOUR ABNORMAL            | 0     | 1     | 0     |
| STOMACH DISCOMFORT             | 0     | 1     | 0     |
| SYNCOPE                        | 0     | 4     | 6     |
| SYNCOPE VASOVAGAL              | 0     | 1     | 0     |
| TRANSIENT ISCHAEMIC            | 0     | 1     | 3     |
| ATTACK                         |       |       |       |
| URTICARIA                      | 0     | 2     | 3     |
| VENTRICULAR                    | 0     | 1     | 4     |
| EXTRASYSTOLES                  |       |       |       |
| VENTRICULAR SEPTAL DEFECT      | 0     | 2     | 1     |
| VERTIGO                        | 0     | 1     | 1     |
| VISION BLURRED                 | 0     | 2     | 1     |
| WEIGHT DECREASED               | 0     | 2     | 0     |
| WOUND HAEMORRHAGE              | 0     | 1     | 0     |
| APPLICATION SITE BLEEDING      | 0     | 0     | 1     |
| APPLICATION SITE               | 0     | 0     | 1     |
| DESQUAMATION                   |       |       |       |
| APPLICATION SITE               | 0     | 0     | 1     |
| DISCOLOURATION                 |       |       |       |
| APPLICATION SITE WARMTH        | 0     | 0     | 2     |
| BALANCE DISORDER               | 0     | 0     | 3     |
| BODY TEMPERATURE               | 0     | 0     | 1     |
| INCREASED                      | 0     | 0     | 1     |
| CELLULITIS  CERLIMEN IMPACTION | 0     | 0     | 1     |
| CERUMEN IMPACTION              | 0     | 0     | 1     |
| COLON CANCER                   | 0     | 0     | 1     |
| COMPLEX PARTIAL SEIZURES       | 0     | 0     | 1     |

| Adverse Events          | Arm A | Arm B | Arm C |
|-------------------------|-------|-------|-------|
| CONJUNCTIVAL            | 0     | 0     | 1     |
| HAEMORRHAGE             |       |       |       |
| COORDINATION ABNORMAL   | 0     | 0     | 1     |
| CYST                    | 0     | 0     | 1     |
| DERMATITIS CONTACT      | 0     | 0     | 2     |
| DYSPHAGIA               | 0     | 0     | 1     |
| DYSPHONIA               | 0     | 0     | 1     |
| ENURESIS                | 0     | 0     | 1     |
| HEMIANOPIA HOMONYMOUS   | 0     | 0     | 1     |
| HOT FLUSH               | 0     | 0     | 1     |
| HYPERSENSITIVITY        | 0     | 0     | 2     |
| INCONTINENCE            | 0     | 0     | 1     |
| INFLAMMATION            | 0     | 0     | 1     |
| JOINT DISLOCATION       | 0     | 0     | 1     |
| MALIGNANT FIBROUS       | 0     | 0     | 2     |
| HISTIOCYTOMA            |       |       |       |
| MUSCULAR WEAKNESS       | 0     | 0     | 2     |
| NASAL MUCOSA BIOPSY     | 0     | 0     | 1     |
| NEUTROPHIL COUNT        | 0     | 0     | 2     |
| INCREASED               |       |       |       |
| OEDEMA                  | 0     | 0     | 2     |
| ONYCHOMYCOSIS           | 0     | 0     | 1     |
| PALPITATIONS            | 0     | 0     | 2     |
| PARAESTHESIA ORAL       | 0     | 0     | 1     |
| PNEUMONIA               | 0     | 0     | 2     |
| RASH ERYTHEMATOUS       | 0     | 0     | 2     |
| RECTAL HAEMORRHAGE      | 0     | 0     | 2     |
| RESTLESSNESS            | 0     | 0     | 2     |
| SECRETION DISCHARGE     | 0     | 0     | 2     |
| SKIN EXFOLIATION        | 0     | 0     | 2     |
| STUPOR                  | 0     | 0     | 1     |
| SUDDEN DEATH            | 0     | 0     | 1     |
| SUPRAVENTRICULAR        | 0     | 0     | 2     |
| TACHYCARDIA             |       |       |       |
| SWELLING                | 0     | 0     | 1     |
| TINNITUS                | 0     | 0     | 1     |
| ULCER                   | 0     | 0     | 1     |
| URINE ANALYSIS ABNORMAL | 0     | 0     | 2     |
| VIRAL INFECTION         | 0     | 0     | 1     |

| Adverse Events                      | Arm A | Arm B | Arm C |
|-------------------------------------|-------|-------|-------|
| WHITE BLOOD CELL COUNT<br>INCREASED | 0     | 0     | 2     |
| WOLFF-PARKINSON-WHITE<br>SYNDROME   | 0     | 0     | 2     |
| WOUND                               | 0     | 0     | 2     |