

**TEAE by PT - Odds Ratio**  
**Safety Analysis Set**  
**Copyright @ mycsg.in**

| Preferred Term                  | Placebo<br>(N=86)<br>n (%) | Active<br>(N=84)<br>n (%) | OR (95% CI)    |
|---------------------------------|----------------------------|---------------------------|----------------|
| Overall                         | 65 ( 75.6%)                | 77 ( 91.7%)               | 3.6 (1.4,8.9)  |
| ABDOMINAL DISCOMFORT            | 0                          | 0                         | -              |
| ABDOMINAL PAIN                  | 1 ( 1.2%)                  | 3 ( 3.6%)                 | 3.1 (0.3,30.9) |
| ACROCHORDON EXCISION            | 0                          | 0                         | -              |
| ACTINIC KERATOSIS               | 0                          | 0                         | -              |
| AGITATION                       | 2 ( 2.3%)                  | 2 ( 2.4%)                 | 1.0 (0.1,7.4)  |
| ALCOHOL USE                     | 0                          | 0                         | -              |
| ALLERGIC GRANULOMATOUS ANGIITIS | 0                          | 0                         | -              |
| ALOPECIA                        | 1 ( 1.2%)                  | 0                         | -              |
| AMNESIA                         | 0                          | 0                         | -              |
| ANXIETY                         | 0                          | 3 ( 3.6%)                 | -              |
| APPLICATION SITE BLEEDING       | 0                          | 1 ( 1.2%)                 | -              |
| APPLICATION SITE DERMATITIS     | 5 ( 5.8%)                  | 9 ( 10.7%)                | 1.9 (0.6,6.1)  |
| APPLICATION SITE DESQUAMATION   | 0                          | 1 ( 1.2%)                 | -              |
| APPLICATION SITE DISCHARGE      | 0                          | 0                         | -              |
| APPLICATION SITE DISCOLOURATION | 0                          | 1 ( 1.2%)                 | -              |
| APPLICATION SITE ERYTHEMA       | 3 ( 3.5%)                  | 12 ( 14.3%)               | 4.6 (1.3,17.0) |
| APPLICATION SITE INDURATION     | 1 ( 1.2%)                  | 0                         | -              |
| APPLICATION SITE IRRITATION     | 3 ( 3.5%)                  | 9 ( 10.7%)                | 3.3 (0.9,12.7) |
| APPLICATION SITE PAIN           | 0                          | 0                         | -              |
| APPLICATION SITE PERSPIRATION   | 0                          | 0                         | -              |
| APPLICATION SITE PRURITUS       | 6 ( 7.0%)                  | 22 ( 26.2%)               | 4.7 (1.8,12.4) |

***TEAE by PT - Odds Ratio***  
***Safety Analysis Set***  
***Copyright @ mycsg.in***

| <b>Preferred Term</b>                  | <b>Placebo<br/>(N=86)<br/>n (%)</b> | <b>Active<br/>(N=84)<br/>n (%)</b> | <b>OR (95% CI)</b> |
|--|-------------------------------------|------------------------------------|--------------------|
| APPLICATION SITE REACTION              | 1 ( 1.2%)                           | 0                                  | -                  |
| APPLICATION SITE SWELLING              | 0                                   | 1 ( 1.2%)                          | -                  |
| APPLICATION SITE URTICARIA             | 0                                   | 2 ( 2.4%)                          | -                  |
| APPLICATION SITE VESICLES              | 1 ( 1.2%)                           | 4 ( 4.8%)                          | 4.3 (0.5,38.8)     |
| APPLICATION SITE WARMTH                | 0                                   | 1 ( 1.2%)                          | -                  |
| ARTHRALGIA                             | 1 ( 1.2%)                           | 2 ( 2.4%)                          | 2.1 (0.2,23.3)     |
| ARTHRITIS                              | 0                                   | 0                                  | -                  |
| ASTHENIA                               | 1 ( 1.2%)                           | 0                                  | -                  |
| ATRIAL FIBRILLATION                    | 1 ( 1.2%)                           | 1 ( 1.2%)                          | 1.0 (0.1,16.6)     |
| ATRIAL FLUTTER                         | 0                                   | 1 ( 1.2%)                          | -                  |
| ATRIAL HYPERTROPHY                     | 1 ( 1.2%)                           | 0                                  | -                  |
| ATRIOVENTRICULAR BLOCK FIRST DEGREE    | 1 ( 1.2%)                           | 1 ( 1.2%)                          | 1.0 (0.1,16.6)     |
| ATRIOVENTRICULAR BLOCK SECOND DEGREE   | 1 ( 1.2%)                           | 0                                  | -                  |
| BACK PAIN                              | 1 ( 1.2%)                           | 1 ( 1.2%)                          | 1.0 (0.1,16.6)     |
| BALANCE DISORDER                       | 0                                   | 1 ( 1.2%)                          | -                  |
| BENIGN PROSTATIC HYPERPLASIA           | 1 ( 1.2%)                           | 0                                  | -                  |
| BIOPSY                                 | 0                                   | 0                                  | -                  |
| BIOPSY PROSTATE                        | 0                                   | 0                                  | -                  |
| BLISTER                                | 0                                   | 5 ( 6.0%)                          | -                  |
| BLOOD ALKALINE PHOSPHATASE INCREASED   | 1 ( 1.2%)                           | 0                                  | -                  |
| BLOOD CHOLESTEROL INCREASED            | 0                                   | 0                                  | -                  |
| BLOOD CREATINE PHOSPHOKINASE INCREASED | 1 ( 1.2%)                           | 0                                  | -                  |
| BLOOD GLUCOSE INCREASED                | 0                                   | 1 ( 1.2%)                          | -                  |

**TEAE by PT - Odds Ratio**  
**Safety Analysis Set**  
**Copyright @ mycsg.in**

| <b>Preferred Term</b>      | <b>Placebo<br/>(N=86)<br/>n (%)</b> | <b>Active<br/>(N=84)<br/>n (%)</b> | <b>OR (95% CI)</b> |
|----------------------------|-------------------------------------|------------------------------------|--------------------|
| BLOOD URINE PRESENT        | 1 ( 1.2%)                           | 0                                  | -                  |
| BODY TEMPERATURE INCREASED | 0                                   | 1 ( 1.2%)                          | -                  |
| BRADYCARDIA                | 1 ( 1.2%)                           | 0                                  | -                  |
| BRONCHITIS                 | 1 ( 1.2%)                           | 0                                  | -                  |
| BUNDLE BRANCH BLOCK LEFT   | 1 ( 1.2%)                           | 0                                  | -                  |
| BUNDLE BRANCH BLOCK RIGHT  | 1 ( 1.2%)                           | 1 ( 1.2%)                          | 1.0 (0.1,16.6)     |
| BURNING SENSATION          | 0                                   | 0                                  | -                  |
| CALCULUS URETHRAL          | 0                                   | 0                                  | -                  |
| CARDIAC DISORDER           | 0                                   | 0                                  | -                  |
| CARDIAC FAILURE CONGESTIVE | 1 ( 1.2%)                           | 0                                  | -                  |
| CATARACT OPERATION         | 1 ( 1.2%)                           | 1 ( 1.2%)                          | 1.0 (0.1,16.6)     |
| CELLULITIS                 | 0                                   | 1 ( 1.2%)                          | -                  |
| CERUMEN IMPACTION          | 0                                   | 1 ( 1.2%)                          | -                  |
| CERVICITIS                 | 1 ( 1.2%)                           | 0                                  | -                  |
| CHEST DISCOMFORT           | 0                                   | 0                                  | -                  |
| CHEST PAIN                 | 0                                   | 0                                  | -                  |
| CHILLS                     | 1 ( 1.2%)                           | 1 ( 1.2%)                          | 1.0 (0.1,16.6)     |
| COGNITIVE DISORDER         | 0                                   | 0                                  | -                  |
| COLD SWEAT                 | 1 ( 1.2%)                           | 0                                  | -                  |
| COLON CANCER               | 0                                   | 1 ( 1.2%)                          | -                  |
| COMPLETED SUICIDE          | 1 ( 1.2%)                           | 0                                  | -                  |
| COMPLEX PARTIAL SEIZURES   | 0                                   | 1 ( 1.2%)                          | -                  |
| CONFUSIONAL STATE          | 2 ( 2.3%)                           | 3 ( 3.6%)                          | 1.6 (0.3,9.6)      |

**TEAE by PT - Odds Ratio**  
**Safety Analysis Set**  
**Copyright @ mycsg.in**

| <b>Preferred Term</b>    | <b>Placebo<br/>(N=86)<br/>n (%)</b> | <b>Active<br/>(N=84)<br/>n (%)</b> | <b>OR (95% CI)</b> |
|--------------------------|-------------------------------------|------------------------------------|--------------------|
| CONJUNCTIVAL HAEMORRHAGE | 0                                   | 1 ( 1.2%)                          | -                  |
| CONJUNCTIVITIS           | 1 ( 1.2%)                           | 0                                  | -                  |
| CONSTIPATION             | 1 ( 1.2%)                           | 0                                  | -                  |
| CONTUSION                | 1 ( 1.2%)                           | 1 ( 1.2%)                          | 1.0 (0.1,16.6)     |
| COORDINATION ABNORMAL    | 0                                   | 1 ( 1.2%)                          | -                  |
| COUGH                    | 1 ( 1.2%)                           | 5 ( 6.0%)                          | 5.4 (0.6,47.1)     |
| CYSTITIS                 | 1 ( 1.2%)                           | 0                                  | -                  |
| CYSTOSCOPY               | 1 ( 1.2%)                           | 0                                  | -                  |
| DECREASED APPETITE       | 1 ( 1.2%)                           | 0                                  | -                  |
| DEHYDRATION              | 1 ( 1.2%)                           | 0                                  | -                  |
| DELIRIUM                 | 0                                   | 0                                  | -                  |
| DELUSION                 | 1 ( 1.2%)                           | 0                                  | -                  |
| DEPRESSED MOOD           | 0                                   | 1 ( 1.2%)                          | -                  |
| DERMATITIS CONTACT       | 0                                   | 1 ( 1.2%)                          | -                  |
| DIABETES MELLITUS        | 1 ( 1.2%)                           | 0                                  | -                  |
| DIARRHOEA                | 9 ( 10.5%)                          | 4 ( 4.8%)                          | 0.4 (0.1,1.4)      |
| DISORIENTATION           | 1 ( 1.2%)                           | 0                                  | -                  |
| DIZZINESS                | 2 ( 2.3%)                           | 8 ( 9.5%)                          | 4.4 (0.9,21.5)     |
| DRUG ERUPTION            | 1 ( 1.2%)                           | 0                                  | -                  |
| DYSPEPSIA                | 1 ( 1.2%)                           | 1 ( 1.2%)                          | 1.0 (0.1,16.6)     |
| DYSPHAGIA                | 0                                   | 1 ( 1.2%)                          | -                  |
| DYSPHONIA                | 0                                   | 1 ( 1.2%)                          | -                  |
| DYSPNOEA                 | 1 ( 1.2%)                           | 1 ( 1.2%)                          | 1.0 (0.1,16.6)     |

**TEAE by PT - Odds Ratio**  
**Safety Analysis Set**  
**Copyright @ mycsg.in**

| Preferred Term                               | Placebo<br>(N=86)<br>n (%) | Active<br>(N=84)<br>n (%) | OR (95% CI)    |
|--|----------------------------|---------------------------|----------------|
| DYSURIA                                      | 1 ( 1.2%)                  | 1 ( 1.2%)                 | 1.0 (0.1,16.6) |
| EAR INFECTION                                | 2 ( 2.3%)                  | 0                         | -              |
| EAR PAIN                                     | 1 ( 1.2%)                  | 0                         | -              |
| ELECTROCARDIOGRAM ST SEGMENT DEPRESSION      | 4 ( 4.7%)                  | 1 ( 1.2%)                 | 0.2 (0.0,2.3)  |
| ELECTROCARDIOGRAM T WAVE AMPLITUDE DECREASED | 1 ( 1.2%)                  | 1 ( 1.2%)                 | 1.0 (0.1,16.6) |
| ELECTROCARDIOGRAM T WAVE INVERSION           | 2 ( 2.3%)                  | 1 ( 1.2%)                 | 0.5 (0.0,5.7)  |
| EMPHYSEMA                                    | 1 ( 1.2%)                  | 0                         | -              |
| EPISTAXIS                                    | 0                          | 1 ( 1.2%)                 | -              |
| ERYTHEMA                                     | 8 ( 9.3%)                  | 14 ( 16.7%)               | 2.0 (0.8,4.9)  |
| EXCORIATION                                  | 2 ( 2.3%)                  | 1 ( 1.2%)                 | 0.5 (0.0,5.7)  |
| EYE ALLERGY                                  | 1 ( 1.2%)                  | 0                         | -              |
| EYE LASER SURGERY                            | 1 ( 1.2%)                  | 0                         | -              |
| EYE PRURITUS                                 | 1 ( 1.2%)                  | 0                         | -              |
| EYE SWELLING                                 | 1 ( 1.2%)                  | 0                         | -              |
| FACIAL BONES FRACTURE                        | 0                          | 0                         | -              |
| FALL   | 1 ( 1.2%)                  | 2 ( 2.4%)                 | 2.1 (0.2,23.3) |
| FATIGUE                                      | 1 ( 1.2%)                  | 5 ( 6.0%)                 | 5.4 (0.6,47.1) |
| FEELING ABNORMAL                             | 0                          | 0                         | -              |
| FEELING COLD                                 | 0                          | 0                         | -              |
| FLANK PAIN                                   | 0                          | 0                         | -              |
| FLATULENCE                                   | 1 ( 1.2%)                  | 0                         | -              |
| FOOD CRAVING                                 | 1 ( 1.2%)                  | 1 ( 1.2%)                 | 1.0 (0.1,16.6) |
| GASTROENTERITIS VIRAL                        | 1 ( 1.2%)                  | 0                         | -              |

**TEAE by PT - Odds Ratio**  
**Safety Analysis Set**  
**Copyright @ mycsg.in**

| Preferred Term                   | Placebo<br>(N=86)<br>n (%) | Active<br>(N=84)<br>n (%) | OR (95% CI)    |
|----------------------------------|----------------------------|---------------------------|----------------|
| GASTROINTESTINAL HAEMORRHAGE     | 0                          | 0                         | -              |
| GASTROOESOPHAGEAL REFLUX DISEASE | 1 ( 1.2%)                  | 0                         | -              |
| GLOSSITIS                        | 1 ( 1.2%)                  | 0                         | -              |
| HAEMOPTYSIS                      | 1 ( 1.2%)                  | 0                         | -              |
| HALLUCINATION                    | 0                          | 0                         | -              |
| HALLUCINATION, VISUAL            | 0                          | 0                         | -              |
| HEADACHE                         | 3 ( 3.5%)                  | 3 ( 3.6%)                 | 1.0 (0.2,5.2)  |
| HEART RATE INCREASED             | 1 ( 1.2%)                  | 0                         | -              |
| HEART RATE IRREGULAR             | 1 ( 1.2%)                  | 0                         | -              |
| HEMIANOPIA HOMONYMOUS            | 0                          | 1 ( 1.2%)                 | -              |
| HIATUS HERNIA                    | 1 ( 1.2%)                  | 0                         | -              |
| HIP FRACTURE                     | 1 ( 1.2%)                  | 0                         | -              |
| HORDEOLUM                        | 0                          | 0                         | -              |
| HOT FLUSH                        | 0                          | 1 ( 1.2%)                 | -              |
| HYPERBILIRUBINAEMIA              | 1 ( 1.2%)                  | 0                         | -              |
| HYPERHIDROSIS                    | 2 ( 2.3%)                  | 4 ( 4.8%)                 | 2.1 (0.4,11.8) |
| HYPERSENSITIVITY                 | 0                          | 1 ( 1.2%)                 | -              |
| HYPERSONMIA                      | 0                          | 0                         | -              |
| HYPERTENSION                     | 1 ( 1.2%)                  | 1 ( 1.2%)                 | 1.0 (0.1,16.6) |
| HYPONATRAEMIA                    | 1 ( 1.2%)                  | 0                         | -              |
| HYPOTENSION                      | 2 ( 2.3%)                  | 1 ( 1.2%)                 | 0.5 (0.0,5.7)  |
| INCONTINENCE                     | 0                          | 1 ( 1.2%)                 | -              |
| INCREASED APPETITE               | 1 ( 1.2%)                  | 0                         | -              |

***TEAE by PT - Odds Ratio***  
***Safety Analysis Set***  
***Copyright @ mycsg.in***

| <b>Preferred Term</b>             | <b>Placebo<br/>(N=86)<br/>n (%)</b> | <b>Active<br/>(N=84)<br/>n (%)</b> | <b>OR (95% CI)</b> |
|-----------------------------------|-------------------------------------|------------------------------------|--------------------|
| INFLAMMATION                      | 0                                   | 1 ( 1.2%)                          | -                  |
| INFLUENZA                         | 1 ( 1.2%)                           | 1 ( 1.2%)                          | 1.0 (0.1,16.6)     |
| INSOMNIA                          | 2 ( 2.3%)                           | 0                                  | -                  |
| IRRITABILITY                      | 1 ( 1.2%)                           | 1 ( 1.2%)                          | 1.0 (0.1,16.6)     |
| JOINT DISLOCATION                 | 0                                   | 1 ( 1.2%)                          | -                  |
| LETHARGY                          | 0                                   | 1 ( 1.2%)                          | -                  |
| LIBIDO DECREASED                  | 0                                   | 0                                  | -                  |
| LISTLESS                          | 0                                   | 0                                  | -                  |
| LOCALISED INFECTION               | 1 ( 1.2%)                           | 0                                  | -                  |
| LOWER RESPIRATORY TRACT INFECTION | 0                                   | 0                                  | -                  |
| MALAISE                           | 0                                   | 1 ( 1.2%)                          | -                  |
| MALIGNANT FIBROUS HISTIOCYTOMA    | 0                                   | 1 ( 1.2%)                          | -                  |
| MICTURITION URGENCY               | 1 ( 1.2%)                           | 1 ( 1.2%)                          | 1.0 (0.1,16.6)     |
| MUSCLE SPASMS                     | 0                                   | 1 ( 1.2%)                          | -                  |
| MUSCULAR WEAKNESS                 | 0                                   | 1 ( 1.2%)                          | -                  |
| MYALGIA                           | 0                                   | 0                                  | -                  |
| MYOCARDIAL INFARCTION             | 4 ( 4.7%)                           | 2 ( 2.4%)                          | 0.5 (0.1,2.8)      |
| NASAL CONGESTION                  | 3 ( 3.5%)                           | 1 ( 1.2%)                          | 0.3 (0.0,3.3)      |
| NASAL MUCOSA BIOPSY               | 0                                   | 1 ( 1.2%)                          | -                  |
| NASOPHARYNGITIS                   | 2 ( 2.3%)                           | 4 ( 4.8%)                          | 2.1 (0.4,11.8)     |
| NAUSEA                            | 3 ( 3.5%)                           | 3 ( 3.6%)                          | 1.0 (0.2,5.2)      |
| NEPHROLITHIASIS                   | 1 ( 1.2%)                           | 0                                  | -                  |
| NIGHTMARE                         | 0                                   | 0                                  | -                  |

**TEAE by PT - Odds Ratio**  
**Safety Analysis Set**  
**Copyright @ mycsg.in**

| Preferred Term                                    | Placebo<br>(N=86)<br>n (%) | Active<br>(N=84)<br>n (%) | OR (95% CI)   |
|---|----------------------------|---------------------------|---------------|
| OEDEMA  | 0                          | 2 ( 2.4%)                 | -             |
| OEDEMA PERIPHERAL                                 | 2 ( 2.3%)                  | 1 ( 1.2%)                 | 0.5 (0.0,5.7) |
| ORTHOSTATIC HYPOTENSION                           | 1 ( 1.2%)                  | 0                         | -             |
| PAIN  | 0                          | 1 ( 1.2%)                 | -             |
| PAIN IN EXTREMITY                                 | 1 ( 1.2%)                  | 0                         | -             |
| PALPITATIONS                                      | 0                          | 2 ( 2.4%)                 | -             |
| PARAESTHESIA                                      | 0                          | 0                         | -             |
| PARAESTHESIA ORAL                                 | 0                          | 1 ( 1.2%)                 | -             |
| PARKINSON'S DISEASE                               | 1 ( 1.2%)                  | 0                         | -             |
| PAROSMIA  | 0                          | 0                         | -             |
| PARTIAL SEIZURES WITH SECONDARY<br>GENERALISATION | 0                          | 0                         | -             |
| PELVIC PAIN                                       | 1 ( 1.2%)                  | 0                         | -             |
| PHARYNGEAL ERYTHEMA                               | 0                          | 0                         | -             |
| PHARYNGOLARYNGEAL PAIN                            | 0                          | 1 ( 1.2%)                 | -             |
| PNEUMONIA   | 0                          | 1 ( 1.2%)                 | -             |
| POLLAKIURIA                                       | 1 ( 1.2%)                  | 0                         | -             |
| POSTNASAL DRIP                                    | 1 ( 1.2%)                  | 0                         | -             |
| PRODUCTIVE COUGH                                  | 0                          | 0                         | -             |
| PROSTATE CANCER                                   | 0                          | 0                         | -             |
| PRURITUS  | 8 ( 9.3%)                  | 21 ( 25.0%)               | 3.3 (1.3,7.8) |
| PRURITUS GENERALISED                              | 0                          | 1 ( 1.2%)                 | -             |
| PSYCHOMOTOR HYPERACTIVITY                         | 1 ( 1.2%)                  | 0                         | -             |
| PYREXIA   | 2 ( 2.3%)                  | 0                         | -             |



***TEAE by PT - Odds Ratio***  
***Safety Analysis Set***  
***Copyright @ mycsg.in***

| <b>Preferred Term</b>        | <b>Placebo<br/>(N=86)<br/>n (%)</b> | <b>Active<br/>(N=84)<br/>n (%)</b> | <b>OR (95% CI)</b> |
|------------------------------|-------------------------------------|------------------------------------|--------------------|
| RALES                        | 1 ( 1.2%)                           | 0                                  | -                  |
| RASH                         | 5 ( 5.8%)                           | 13 ( 15.5%)                        | 3.0 (1.0,8.7)      |
| RASH ERYTHEMATOUS            | 0                                   | 1 ( 1.2%)                          | -                  |
| RASH MACULO-PAPULAR          | 0                                   | 0                                  | -                  |
| RASH PRURITIC                | 0                                   | 1 ( 1.2%)                          | -                  |
| RECTAL HAEMORRHAGE           | 0                                   | 1 ( 1.2%)                          | -                  |
| RESPIRATORY TRACT CONGESTION | 0                                   | 0                                  | -                  |
| RESTLESSNESS                 | 0                                   | 1 ( 1.2%)                          | -                  |
| RHINITIS                     | 0                                   | 0                                  | -                  |
| RHINORRHOEA                  | 0                                   | 1 ( 1.2%)                          | -                  |
| SALIVARY HYPERSECRETION      | 0                                   | 0                                  | -                  |
| SECRETION DISCHARGE          | 0                                   | 1 ( 1.2%)                          | -                  |
| SHOULDER PAIN                | 1 ( 1.2%)                           | 2 ( 2.4%)                          | 2.1 (0.2,23.3)     |
| SINUS ARRHYTHMIA             | 1 ( 1.2%)                           | 0                                  | -                  |
| SINUS BRADYCARDIA            | 2 ( 2.3%)                           | 7 ( 8.3%)                          | 3.8 (0.8,18.9)     |
| SKIN EXFOLIATION             | 0                                   | 1 ( 1.2%)                          | -                  |
| SKIN IRRITATION              | 3 ( 3.5%)                           | 6 ( 7.1%)                          | 2.1 (0.5,8.8)      |
| SKIN LACERATION              | 1 ( 1.2%)                           | 2 ( 2.4%)                          | 2.1 (0.2,23.3)     |
| SKIN LESION EXCISION         | 0                                   | 0                                  | -                  |
| SKIN ODOUR ABNORMAL          | 0                                   | 0                                  | -                  |
| SKIN ULCER                   | 1 ( 1.2%)                           | 0                                  | -                  |
| SOMNOLENCE                   | 2 ( 2.3%)                           | 3 ( 3.6%)                          | 1.6 (0.3,9.6)      |
| STOMACH DISCOMFORT           | 0                                   | 0                                  | -                  |

***TEAE by PT - Odds Ratio***  
***Safety Analysis Set***  
***Copyright @ mycsg.in***

| <b>Preferred Term</b>             | <b>Placebo<br/>(N=86)<br/>n (%)</b> | <b>Active<br/>(N=84)<br/>n (%)</b> | <b>OR (95% CI)</b> |
|-----------------------------------|-------------------------------------|------------------------------------|--------------------|
| STUPOR                            | 0                                   | 1 ( 1.2%)                          | -                  |
| SUDDEN DEATH                      | 0                                   | 1 ( 1.2%)                          | -                  |
| SUPRAVENTRICULAR EXTRASYSTOLES    | 1 ( 1.2%)                           | 1 ( 1.2%)                          | 1.0 (0.1,16.6)     |
| SUPRAVENTRICULAR TACHYCARDIA      | 0                                   | 1 ( 1.2%)                          | -                  |
| SWELLING                          | 0                                   | 1 ( 1.2%)                          | -                  |
| SYNCOPE                           | 0                                   | 4 ( 4.8%)                          | -                  |
| SYNCOPE VASOVAGAL                 | 0                                   | 0                                  | -                  |
| TACHYCARDIA                       | 1 ( 1.2%)                           | 0                                  | -                  |
| TRANSIENT ISCHAEMIC ATTACK        | 0                                   | 2 ( 2.4%)                          | -                  |
| ULCER                             | 0                                   | 1 ( 1.2%)                          | -                  |
| UPPER RESPIRATORY TRACT INFECTION | 6 ( 7.0%)                           | 1 ( 1.2%)                          | 0.2 (0.0,1.4)      |
| URINARY TRACT INFECTION           | 2 ( 2.3%)                           | 0                                  | -                  |
| URTICARIA                         | 0                                   | 1 ( 1.2%)                          | -                  |
| VAGINAL MYCOSIS                   | 1 ( 1.2%)                           | 0                                  | -                  |
| VENTRICULAR EXTRASYSTOLES         | 0                                   | 2 ( 2.4%)                          | -                  |
| VENTRICULAR HYPERTROPHY           | 1 ( 1.2%)                           | 0                                  | -                  |
| VENTRICULAR SEPTAL DEFECT         | 0                                   | 1 ( 1.2%)                          | -                  |
| VERTIGO                           | 0                                   | 1 ( 1.2%)                          | -                  |
| VIRAL INFECTION                   | 0                                   | 1 ( 1.2%)                          | -                  |
| VISION BLURRED                    | 0                                   | 1 ( 1.2%)                          | -                  |
| VOMITING                          | 3 ( 3.5%)                           | 3 ( 3.6%)                          | 1.0 (0.2,5.2)      |
| WEIGHT DECREASED                  | 0                                   | 0                                  | -                  |
| WOLFF-PARKINSON-WHITE SYNDROME    | 0                                   | 1 ( 1.2%)                          | -                  |

***TEAE by PT - Odds Ratio***  
***Safety Analysis Set***  
***Copyright @ mycsg.in***

| Preferred Term    | Placebo<br>(N=86)<br>n (%) | Active<br>(N=84)<br>n (%) | OR (95% CI) |
|-------------------|----------------------------|---------------------------|-------------|
| WOUND             | 0                          | 1 ( 1.2%)                 | -           |
| WOUND HAEMORRHAGE | 0                          | 0                         | -           |
|                   |                            |                           |             |