11. Adverse Events

11.3. Treatment-Emergent AEs by Maximum Severity

OLE Population

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Overall (N=6) n % | | |  |
| System Organ Class    Preferred Term | Mild | Moderate | Severe |  |
|  | | | | |
| Subject with at least one treatment-emergent AE | 2 ( 33.3) | 1 ( 16.7) |  |  |
|  | | | | |
| Gastrointestinal disorders | 2 ( 33.3) | 1 ( 16.7) |  |  |
| Diarrhoea | 2 ( 33.3) | 1 ( 16.7) |  |  |
| Salivary hypersecretion | 1 ( 16.7) |  |  |  |
|  | | | | |
| Investigations | 1 ( 16.7) | 1 ( 16.7) |  |  |
| Gamma-glutamyltransferase increased | 1 ( 16.7) | 1 ( 16.7) |  |  |
| Source: Listing 11.1 Only adverse events that were considered treatment emergent in the OLE period are displayed in this table. For each SOC/PT, maximum severity is used. If a subject has multiple events within a system organ class or preferred term, the subject is counted once. Events are sorted by decreased SOCs, PTs frequencies on all subjects without taking into account the severity. In case of equal frequency, alphabetic order is used. Output ID: T-AESEV 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-AESEV.sas                                                                                                     Page 1 of 1 | | | | |