11. Adverse Events

11.1. Treatment-Emergent AEs

OLE Population

|  |  |
| --- | --- |
| System Organ Class    Preferred Term | Overall (N=6) n % |
|  | |
| Subject with at least one treatment-emergent AE | 3 ( 50.0) |
|  | |
| Gastrointestinal disorders | 3 ( 50.0) |
| Diarrhoea | 3 ( 50.0) |
| Salivary hypersecretion | 1 ( 16.7) |
|  | |
| Investigations | 2 ( 33.3) |
| Gamma-glutamyltransferase increased | 2 ( 33.3) |
| Source: Listing 11.1 Only adverse events that were considered treatment emergent in the OLE period are displayed in this table. 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 the total column. In case of equal frequency, alphabetic order is used. Output ID: T-AE 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-AE.sas                                                                                     Page 1 of 1 | |