| StudyID/Eudra CT Number | CaseID/Subject Number | Duplicate | Country/Gender/Age/Race | Suspect Drug | Dose(frequency)/Route/Formulation | Treatment Start Date | Treatment Stop Date | System Organ Class | Adverse Reaction(s) | Expectedness/Seriousness/Drop-out | Outcome | Date of Onset | Comments(Investigator's Causality) |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 14570A | 14570A-CA002-S2577 |  | CANADA  Male  60Years  White | PLACEBO | 0mg(QD)  ORAL  TABLET | 07Jan2015 | 13Jan2015 | General disorders and administration site conditions | Pain | Unexpected  Non-serious  No | Recovered/Resolved | 12May2015 | Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 14Jan2015 | 20Jan2015 | Nervous system disorders | Extrapyramidal disorder | Expected  Non-serious  Yes | Recovered/Resolved | 12May2015 | Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 21Jan2015 | 03Feb2015 | Investigations | Blood creatine phosphokinase increased | Unexpected  Non-serious  No | Recovered/Resolved | 12May2015 | Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 04Feb2015 | 17Feb2015 |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 18Feb2015 | 03Mar2015 |
| DUMMY1 | 1mg(QD)  ORAL  TABLET | 04Mar2015 | 11Mar2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 12Mar2015 | 17Mar2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 18Mar2015 | 31Mar2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 01Apr2015 | 13Apr2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 14Apr2015 | 28Apr2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 29Apr2015 | 12May2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 13May2015 | 14May2015 |
| 14570A | 14570A-DE009-S3398 |  | GERMANY  Male  58Years  White | PLACEBO | 0mg(QD)  ORAL  TABLET | 28Aug2015 | 03Sep2015 | Infections and infestations | Cystitis | Unexpected  Non-serious  No | Recovered/Resolved | 15Sep2015 | Not Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 04Sep2015 | 08Sep2015 | Infections and infestations | Urinary tract infection | Unexpected  Non-serious  No | Recovered/Resolved | 02Nov2015 | Not Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 09Sep2015 | 21Sep2015 | General disorders and administration site conditions | Feeling of body temperature change | Unexpected  Non-serious  No | Recovered/Resolved | 13Nov2015 | Not Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 22Sep2015 | 04Oct2015 | Psychiatric disorders | Depressive symptom | Unexpected  Non-serious  Yes | Not Recovered/Not Resolved | 08Jan2016 | Possibly Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 05Oct2015 | 18Oct2015 |
| DUMMY2 | 1mg(QD)  ORAL  TABLET | 19Oct2015 | 26Oct2015 |
| DUMMY2 | 2mg(QD)  ORAL  TABLET | 27Oct2015 | 03Nov2015 |
| DUMMY2 | 2mg(QD)  ORAL  TABLET | 04Nov2015 | 16Nov2015 |
| DUMMY2 | 2mg(QD)  ORAL  TABLET | 17Nov2015 | 30Nov2015 |
| DUMMY2 | 2mg(QD)  ORAL  TABLET | 30Nov2015 | 14Dec2015 |
| DUMMY2 | 2mg(QD)  ORAL  TABLET | 15Dec2015 | 28Dec2015 |
| DUMMY2 | 2mg(QD)  ORAL  TABLET | 28Dec2015 | 08Jan2016 |
| 14570A | 14570A-DE014-S3015 |  | GERMANY  Male  42Years  White | PLACEBO | 0mg(QD)  ORAL  TABLET | 22Apr2015 | 28Apr2015 | General disorders and administration site conditions | Fatigue | Expected  Non-serious  No | Recovered/Resolved | 23Apr2015 | Not Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 29Apr2015 | 05May2015 | Gastrointestinal disorders | Dry mouth | Expected  Non-serious  No | Recovered/Resolved | 23Apr2015 | Not Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 06May2015 | 19May2015 | Gastrointestinal disorders | Nausea | Unexpected  Non-serious  No | Recovered/Resolved | 29May2015 | Not Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 20May2015 | 02Jun2015 | Investigations | Blood pressure increased | Unexpected  Non-serious  No | Recovered/Resolved | 29Jul2015 | Not Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 03Jun2015 | 16Jun2015 | Nervous system disorders | Headache | Unexpected  Non-serious  No | Recovered/Resolved | 14Aug2015 | Not Related |
| DUMMY1 | 1mg(QD)  ORAL  TABLET | 17Jun2015 | 24Jun2015 | Investigations | Blood pressure increased | Unexpected  Non-serious  No | Recovered/Resolved | 25Aug2015 | Not Related |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 25Jun2015 | 30Jun2015 | Injury, poisoning and procedural complications | Muscle strain | Unexpected  Non-serious  No | Recovered/Resolved | 25Oct2015 | Not Related |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 01Jul2015 | 14Jul2015 | Investigations | Blood creatine phosphokinase increased | Unexpected  Non-serious  Yes | Recovered/Resolved | 27Oct2015 | Not Related |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 15Jul2015 | 29Jul2015 | Investigations | Blood pressure increased | Unexpected  Non-serious  No | Recovered/Resolved | 27Oct2015 | Not Related |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 30Jul2015 | 18Aug2015 | Infections and infestations | Nasopharyngitis | Expected  Non-serious  No | Recovered/Resolved | 25Nov2015 | Not Related |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 19Aug2015 | 25Aug2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 26Aug2015 | 29Sep2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 30Sep2015 | 27Oct2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 28Oct2015 | 17Nov2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 18Nov2015 | 01Dec2015 |
| 14570A | 14570A-DE015-S3103 |  | GERMANY  Female  53Years  White | PLACEBO | 0mg(QD)  ORAL  TABLET | 09May2015 | 18May2015 | Psychiatric disorders | Hallucination, visual | Unexpected  Non-serious  Yes | Recovered/Resolved | 19Jul2015 | Possibly Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 19May2015 | 26May2015 |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 27May2015 | 02Jun2015 |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 03Jun2015 | 16Jun2015 |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 17Jun2015 | 30Jun2015 |
| DUMMY1 | 1mg(QD)  ORAL  TABLET | 01Jul2015 | 08Jul2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 09Jul2015 | 14Jul2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 15Jul2015 | 28Jul2015 |
| 14570A | 14570A-DE016-S2529 |  | GERMANY  Female  19Years  White | PLACEBO | 0mg(QD)  ORAL  TABLET | 06Dec2014 | 11Dec2014 | Pregnancy, puerperium and perinatal conditions | Pregnancy | Unexpected  Non-serious  Yes | Recovered/Resolved | 17Jul2015 | Not Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 12Dec2014 | 18Dec2014 | Pregnancy, puerperium and perinatal conditions | Abortion | Unexpected  Non-serious  No | Recovered/Resolved | 22Jul2015 | Not Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 18Dec2014 | 18Dec2014 |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 19Dec2014 | 09Jan2015 |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 10Jan2015 | 15Jan2015 |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 16Jan2015 | 29Jan2015 |
| DUMMY1 | 1mg(QD)  ORAL  TABLET | 30Jan2015 | 06Feb2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 07Feb2015 | 12Feb2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 13Feb2015 | 23Feb2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 24Feb2015 | 12Mar2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 13Mar2015 | 26Mar2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 27Mar2015 | 09Apr2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 09Apr2015 | 09Apr2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 10Apr2015 | 11May2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 11May2015 | 11May2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 12May2015 | 08Jun2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 09Jun2015 | 06Jul2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 07Jul2015 | 15Jul2015 |
| 14570A | 14570A-DE016-S3208 |  | GERMANY  Male  68Years  White | PLACEBO | 0mg(QD)  ORAL  TABLET | 16Jun2015 | 24Jun2015 | Nervous system disorders | Ataxia | Unexpected  Non-serious  Yes | Recovered/Resolved | 04Oct2015 | Possibly Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 25Jun2015 | 01Jul2015 |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 02Jul2015 | 15Jul2015 |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 16Jul2015 | 29Jul2015 |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 30Jul2015 | 12Aug2015 |
| DUMMY2 | 1mg(QD)  ORAL  TABLET | 13Aug2015 | 20Aug2015 |
| DUMMY2 | 2mg(QD)  ORAL  TABLET | 21Aug2015 | 26Aug2015 |
| DUMMY2 | 2mg(QD)  ORAL  TABLET | 27Aug2015 | 08Sep2015 |
| DUMMY2 | 2mg(QD)  ORAL  TABLET | 09Sep2015 | 23Sep2015 |
| DUMMY2 | 2mg(QD)  ORAL  TABLET | 24Sep2015 | 02Oct2015 |
| DUMMY2 | 2mg(QD)  ORAL  TABLET | 03Oct2015 | 19Oct2015 |
| 14570A | 14570A-DE017-S2341 |  | GERMANY  Female  46Years  White | PLACEBO | 0mg(QD)  ORAL  TABLET | 29Oct2014 | 03Nov2014 | Psychiatric disorders | Depression | Unexpected  Non-serious  Yes | Not Recovered/Not Resolved | 27Apr2015 | Possibly Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 04Nov2014 | 10Nov2014 |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 11Nov2014 | 24Nov2014 |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 25Nov2014 | 08Dec2014 |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 09Dec2014 | 19Dec2014 |
| DUMMY1 | 1mg(QD)  ORAL  TABLET | 20Dec2014 | 27Dec2014 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 28Dec2014 | 05Jan2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 06Jan2015 | 19Jan2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 20Jan2015 | 02Feb2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 03Feb2015 | 19Feb2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 20Feb2015 | 02Mar2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 02Mar2015 | 02Mar2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 03Mar2015 | 30Mar2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 31Mar2015 | 27Apr2015 |
| 14570A | 14570A-EE002-S3147 |  | ESTONIA  Female  42Years  White | PLACEBO | 0mg(QD)  ORAL  TABLET | 26May2015 | 02Jun2015 | Gastrointestinal disorders | Diarrhoea | Unexpected  Non-serious  Yes | Recovered/Resolved | 06Jul2015 | Not Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 03Jun2015 | 10Jun2015 | Infections and infestations | Upper respiratory tract infection | Unexpected  Non-serious  No | Recovered/Resolved | 15Sep2015 | Not Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 11Jun2015 | 22Jun2015 |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 23Jun2015 | 09Jul2015 |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 10Jul2015 | 22Jul2015 |
| DUMMY1 | 1mg(QD)  ORAL  TABLET | 23Jul2015 | 30Jul2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 31Jul2015 | 05Aug2015 |
| DUMMY1 | 3mg(QD)  ORAL  TABLET | 06Aug2015 | 19Aug2015 |
| DUMMY1 | 3mg(QD)  ORAL  TABLET | 20Aug2015 | 02Sep2015 |
| DUMMY1 | 3mg(QD)  ORAL  TABLET | 03Sep2015 | 17Sep2015 |
| DUMMY1 | 3mg(QD)  ORAL  TABLET | 18Sep2015 | 30Sep2015 |
| DUMMY1 | 3mg(QD)  ORAL  TABLET | 30Sep2015 | 30Sep2015 |
| DUMMY1 | 3mg(QD)  ORAL  TABLET | 01Oct2015 | 28Oct2015 |
| DUMMY1 | 3mg(QD)  ORAL  TABLET | 29Oct2015 | 25Nov2015 |
| DUMMY1 | 3mg(QD)  ORAL  TABLET | 26Nov2015 | 22Dec2015 |
| DUMMY1 | 3mg(QD)  ORAL  TABLET | 23Dec2015 | 05Jan2016 |
| 14570A | 14570A-EE002-S3188 |  | ESTONIA  Male  22Years  White | PLACEBO | 0mg(QD)  ORAL  TABLET | 11Jun2015 | 17Jun2015 | Nervous system disorders | Headache | Unexpected  Non-serious  No | Recovered/Resolved | 27Aug2015 | Possibly Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 18Jun2015 | 22Jun2015 | Nervous system disorders | Headache | Unexpected  Non-serious  No | Recovered/Resolved | 09Sep2015 | Possibly Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 23Jun2015 | 07Jul2015 | General disorders and administration site conditions | Asthenia | Unexpected  Non-serious  Yes | Recovered/Resolved | 01Dec2015 | Possibly Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 08Jul2015 | 22Jul2015 |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 23Jul2015 | 05Aug2015 |
| DUMMY2 | 1mg(QD)  ORAL  TABLET | 06Aug2015 | 13Aug2015 |
| DUMMY2 | 2mg(QD)  ORAL  TABLET | 14Aug2015 | 19Aug2015 |
| DUMMY2 | 3mg(QD)  ORAL  TABLET | 20Aug2015 | 02Sep2015 |
| DUMMY2 | 3mg(QD)  ORAL  TABLET | 03Sep2015 | 16Sep2015 |
| DUMMY2 | 2mg(QD)  ORAL  TABLET | 17Sep2015 | 30Sep2015 |
| DUMMY2 | 2mg(QD)  ORAL  TABLET | 01Oct2015 | 14Oct2015 |
| DUMMY2 | 2mg(QD)  ORAL  TABLET | 15Oct2015 | 11Nov2015 |
| DUMMY2 | 2mg(QD)  ORAL  TABLET | 12Nov2015 | 08Dec2015 |
| DUMMY2 | 2mg(QD)  ORAL  TABLET | 09Dec2015 | 06Jan2016 |
| DUMMY2 | 2mg(QD)  ORAL  TABLET | 07Jan2016 | 20Jan2016 |
| 14570A | 14570A-EE004-S2647 |  | ESTONIA  Female  55Years  White | PLACEBO | 0mg(QD)  ORAL  TABLET | 20Jan2015 | 26Jan2015 | Nervous system disorders | Somnolence | Expected  Non-serious  No | Recovered/Resolved | 27May2015 | Possibly Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 27Jan2015 | 02Feb2015 | Nervous system disorders | Dyskinesia | Unexpected  Non-serious  Yes | Recovered/Resolved | 09Jul2015 | Possibly Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 03Feb2015 | 16Feb2015 |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 17Feb2015 | 02Mar2015 |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 03Mar2015 | 19Mar2015 |
| DUMMY1 | 1mg(QD)  ORAL  TABLET | 20Mar2015 | 27Mar2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 28Mar2015 | 31Mar2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 01Apr2015 | 13Apr2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 14Apr2015 | 27Apr2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 28Apr2015 | 11May2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 11May2015 | 25May2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 26May2015 | 22Jun2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 22Jun2015 | 09Jul2015 |
| 14570A | 14570A-EE004-S2947 |  | ESTONIA  Male  51Years  White | PLACEBO | 0mg(QD)  ORAL  TABLET | 24Mar2015 | 30Mar2015 | Investigations | Weight decreased | Unexpected  Non-serious  No | Recovered/Resolved | 18Jun2015 | Possibly Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 31Mar2015 | 06Apr2015 | Investigations | Aspartate aminotransferase increased | Unexpected  Non-serious  No | Recovered/Resolved | 19Jun2015 | Not Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 07Apr2015 | 20Apr2015 | Investigations | Alanine aminotransferase increased | Unexpected  Non-serious  No | Recovered/Resolved | 19Jun2015 | Not Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 21Apr2015 | 04May2015 | Psychiatric disorders | Insomnia | Expected  Non-serious  No | Recovered/Resolved | 23Jun2015 | Possibly Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 05May2015 | 18May2015 | Psychiatric disorders | Insomnia | Expected  Non-serious  No | Recovered/Resolved | 20Jul2015 | Possibly Related |
| DUMMY1 | 1mg(QD)  ORAL  TABLET | 19May2015 | 26May2015 | Psychiatric disorders | Insomnia | Expected  Non-serious  No | Recovered/Resolved | 31Jul2015 | Possibly Related |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 27May2015 | 01Jun2015 | Psychiatric disorders | Insomnia | Expected  Non-serious  Yes | Recovered/Resolved | 08Sep2015 | Possibly Related |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 01Jun2015 | 18Jun2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 19Jun2015 | 29Jun2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 30Jun2015 | 13Jul2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 14Jul2015 | 30Jul2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 31Jul2015 | 24Aug2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 25Aug2015 | 20Sep2015 |
| 14570A | 14570A-EE004-S3456 |  | ESTONIA  Female  45Years  White | PLACEBO | 0mg(QD)  ORAL  TABLET | 12Sep2015 | 17Sep2015 | Nervous system disorders | Somnolence | Expected  Non-serious  No | Recovered/Resolved | 12Sep2015 | Possibly Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 18Sep2015 | 24Sep2015 | Gastrointestinal disorders | Toothache | Unexpected  Non-serious  No | Recovered/Resolved | 13Oct2015 | Not Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 25Sep2015 | 08Oct2015 | Gastrointestinal disorders | Toothache | Unexpected  Non-serious  No | Recovered/Resolved | 14Nov2015 | Not Related |
| PLACEBO | 0mg(DAY)  ORAL  TABLET | 08Oct2015 | 21Oct2015 | Investigations | Blood pressure increased | Unexpected  Non-serious  No | Recovered/Resolved | 29Dec2015 | Possibly Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 22Oct2015 | 05Nov2015 | Investigations | Weight increased | Expected  Non-serious  Yes | Not Recovered/Not Resolved | 12Jan2016 | Possibly Related |
| DUMMY2 | 1mg(QD)  ORAL  TABLET | 06Nov2015 | 13Nov2015 |
| DUMMY2 | 2mg(QD)  ORAL  TABLET | 14Nov2015 | 19Nov2015 |
| DUMMY2 | 2mg(QD)  ORAL  TABLET | 20Nov2015 | 03Dec2015 |
| DUMMY2 | 2mg(QD)  ORAL  TABLET | 04Dec2015 | 17Dec2015 |
| DUMMY2 | 2mg(QD)  ORAL  TABLET | 18Dec2015 | 29Dec2015 |
| DUMMY2 | 2mg(QD)  ORAL  TABLET | 30Dec2015 | 11Jan2016 |
| 14570A | 14570A-EE005-S2776 |  | ESTONIA  Female  47Years  White | PLACEBO | 0mg(QD)  ORAL  TABLET | 27Feb2015 | 05Mar2015 | Infections and infestations | Viral upper respiratory tract infection | Unexpected  Non-serious  No | Recovered/Resolved | 20May2015 | Not Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 06Mar2015 | 11Mar2015 | Investigations | Weight increased | Expected  Non-serious  Yes | Not Recovered/Not Resolved | 02Jul2015 | Possibly Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 12Mar2015 | 26Mar2015 |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 27Mar2015 | 09Apr2015 |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 10Apr2015 | 23Apr2015 |
| DUMMY2 | 1mg(QD)  ORAL  TABLET | 24Apr2015 | 01May2015 |
| DUMMY2 | 2mg(QD)  ORAL  TABLET | 02May2015 | 07May2015 |
| DUMMY2 | 2mg(QD)  ORAL  TABLET | 08May2015 | 21May2015 |
| DUMMY2 | 2mg(QD)  ORAL  TABLET | 22May2015 | 04Jun2015 |
| DUMMY2 | 2mg(QD)  ORAL  TABLET | 05Jun2015 | 18Jun2015 |
| DUMMY2 | 2mg(QD)  ORAL  TABLET | 19Jun2015 | 01Jul2015 |
| 14570A | 14570A-FI001-S3276 |  | FINLAND  Female  39Years  White | PLACEBO | 0mg(QD)  ORAL  TABLET | 15Jul2015 | 21Jul2015 | Gastrointestinal disorders | Dyspepsia | Expected  Non-serious  No | Not Recovered/Not Resolved | 22Jul2015 | Possibly Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 22Jul2015 | 29Jul2015 | Vascular disorders | Hot flush | Unexpected  Non-serious  No | Not Recovered/Not Resolved | 28Aug2015 | Possibly Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 30Jul2015 | 14Aug2015 | Metabolism and nutrition disorders | Increased appetite | Expected  Non-serious  No | Not Recovered/Not Resolved | 28Aug2015 | Possibly Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 15Aug2015 | 25Aug2015 | General disorders and administration site conditions | Fatigue | Expected  Non-serious  No | Not Recovered/Not Resolved | 28Aug2015 | Possibly Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 26Aug2015 | 03Sep2015 | Skin and subcutaneous tissue disorders | Urticaria | Unexpected  Non-serious  Yes | Recovered/Resolved | 03Sep2015 | Possibly Related |
| DUMMY2 | 1mg(QD)  ORAL  TABLET | 04Sep2015 | 11Sep2015 | Infections and infestations | Cystitis | Unexpected  Non-serious  No | Recovered/Resolved | 05Oct2015 | Not Related |
| DUMMY2 | 2mg(QD)  ORAL  TABLET | 12Sep2015 | 25Sep2015 |
| DUMMY2 | 2mg(QD)  ORAL  TABLET | 26Sep2015 | 06Oct2015 |
| DUMMY2 | 2mg(QD)  ORAL  TABLET | 07Oct2015 | 22Oct2015 |
| DUMMY2 | 4mg(DAY)  ORAL  TABLET | 23Oct2015 | 02Nov2015 |
| DUMMY2 | 2mg(QD)  ORAL  TABLET | 03Nov2015 | 17Nov2015 |
| DUMMY2 | 2mg(QD)  ORAL  TABLET | 18Nov2015 | 16Dec2015 |
| DUMMY2 | 2mg(QD)  ORAL  TABLET | 17Dec2015 | 12Jan2016 |
| DUMMY2 | 2mg(QD)  ORAL  TABLET | 13Jan2016 | 08Feb2016 |
| DUMMY2 | 2mg(QD)  ORAL  TABLET | 09Feb2016 | 25Feb2016 |
| 14570A | 14570A-FI003-S3186 |  | FINLAND  Female  46Years  White | PLACEBO | 0mg(QD)  ORAL  TABLET | 05Jun2015 | 11Jun2015 | Skin and subcutaneous tissue disorders | Acne | Unexpected  Non-serious  No | Not Recovered/Not Resolved | 25May2015 | Not Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 12Jun2015 | 18Jun2015 | Nervous system disorders | Dizziness | Expected  Non-serious  No | Recovered/Resolved | 06Jun2015 | Not Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 19Jun2015 | 01Jul2015 | Gastrointestinal disorders | Nausea | Unexpected  Non-serious  No | Recovered/Resolved | 06Jun2015 | Not Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 02Jul2015 | 17Jul2015 | Nervous system disorders | Paraesthesia | Unexpected  Non-serious  No | Recovered/Resolved | 06Jun2015 | Not Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 18Jul2015 | 28Jul2015 | Infections and infestations | Influenza | Unexpected  Non-serious  No | Recovered/Resolved | 13Jul2015 | Not Related |
| DUMMY2 | 1mg(QD)  ORAL  TABLET | 29Jul2015 | 05Aug2015 | Psychiatric disorders | Restlessness | Expected  Non-serious  No | Recovered/Resolved | 29Aug2015 | Related |
| DUMMY2 | 2mg(QD)  ORAL  TABLET | 06Aug2015 | 10Aug2015 | Reproductive system and breast disorders | Menstruation irregular | Unexpected  Non-serious  No | Not Recovered/Not Resolved | 17Sep2015 | Not Related |
| DUMMY2 | 3mg(QD)  ORAL  TABLET | 11Aug2015 | 25Aug2015 | Psychiatric disorders | Anxiety | Expected  Non-serious  Yes | Not Recovered/Not Resolved | 30Sep2015 | Related |
| DUMMY2 | 3mg(QD)  ORAL  TABLET | 26Aug2015 | 10Sep2015 | Psychiatric disorders | Insomnia | Expected  Non-serious  No | Not Recovered/Not Resolved | 03Oct2015 | Possibly Related |
| DUMMY2 | 2mg(QD)  ORAL  TABLET | 11Sep2015 | 24Sep2015 |
| DUMMY2 | 2mg(QD)  ORAL  TABLET | 25Sep2015 | 07Oct2015 |
| 14570A | 14570A-FI008-S2702 |  | FINLAND  Female  70Years  White | PLACEBO | 0mg(QD)  ORAL  TABLET | 05Feb2015 | 10Feb2015 | General disorders and administration site conditions | Fatigue | Expected  Non-serious  Yes | Recovered/Resolved | 18May2015 | Possibly Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 11Feb2015 | 18Feb2015 |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 19Feb2015 | 03Mar2015 |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 04Mar2015 | 19Mar2015 |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 20Mar2015 | 02Apr2015 |
| DUMMY2 | 1mg(QD)  ORAL  TABLET | 03Apr2015 | 10Apr2015 |
| DUMMY2 | 2mg(QD)  ORAL  TABLET | 11Apr2015 | 15Apr2015 |
| DUMMY2 | 3mg(QD)  ORAL  TABLET | 16Apr2015 | 29Apr2015 |
| DUMMY2 | 3mg(QD)  ORAL  TABLET | 30Apr2015 | 11May2015 |
| DUMMY2 | 3mg(QD)  ORAL  TABLET | 12May2015 | 27May2015 |
| DUMMY2 | 3mg(QD)  ORAL  TABLET | 28May2015 | 11Jun2015 |
| DUMMY2 | 3mg(QD)  ORAL  TABLET | 12Jun2015 | 08Jul2015 |
| DUMMY2 | 3mg(QD)  ORAL  TABLET | 09Jul2015 | 03Aug2015 |
| 14570A | 14570A-GB003-S3411 |  | UNITED KINGDOM  Female  63Years  White | PLACEBO | 0mg(QD)  ORAL  TABLET | 08Sep2015 | 14Sep2015 | Investigations | False positive investigation result | Unexpected  Serious  Yes | Recovered/Resolved | 17Nov2015 | Not Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 15Sep2015 | 28Sep2015 | Nervous system disorders | Restless legs syndrome | Unexpected  Non-serious  No | Not Recovered/Not Resolved | 15Nov2015 | Possibly Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 29Sep2015 | 05Oct2015 |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 06Oct2015 | 19Oct2015 |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 20Oct2015 | 09Nov2015 |
| DUMMY1 | 1mg(QD)  ORAL  TABLET | 10Nov2015 | 16Nov2015 |
| DUMMY1 | 3mg(QD)  ORAL  TABLET |  | 17Nov2015 |
| 14570A | 14570A-GB003-S3447 |  | UNITED KINGDOM  Female  50Years  White | PLACEBO | 0mg(QD)  ORAL  TABLET | 03Sep2015 | 11Sep2015 | Nervous system disorders | Dysarthria | Unexpected  Non-serious  Yes | Recovered/Resolved | 24Dec2015 | Possibly Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 12Sep2015 | 14Sep2015 | Nervous system disorders | Transient ischaemic attack | Unexpected  Non-serious  Yes | Recovered/Resolved | 24Dec2015 | Possibly Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 15Sep2015 | 29Sep2015 |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 30Sep2015 | 14Oct2015 |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 15Oct2015 | 27Oct2015 |
| DUMMY1 | 1mg(QD)  ORAL  TABLET | 28Oct2015 | 04Nov2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 05Nov2015 | 10Nov2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 11Nov2015 | 24Nov2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 25Nov2015 | 08Dec2015 |
| DUMMY1 | 4mg(DAY)  ORAL  TABLET | 09Dec2015 | 22Dec2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 23Dec2015 | 24Dec2015 |
| 14570A | 14570A-GB004-S2785 |  | UNITED KINGDOM  Female  45Years  White | PLACEBO | 0mg(QD)  ORAL  TABLET | 27Feb2015 | 02Mar2015 | General disorders and administration site conditions | Oedema peripheral | Unexpected  Non-serious  No | Recovered/Resolved | 26Apr2015 | Possibly Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 03Mar2015 | 12Mar2015 | Psychiatric disorders | Abnormal dreams | Unexpected  Non-serious  No | Not Recovered/Not Resolved | 04May2015 | Possibly Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 13Mar2015 | 26Mar2015 | Endocrine disorders | Hypothyroidism | Unexpected  Non-serious  Yes | Not Recovered/Not Resolved | 21May2015 | Possibly Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 27Mar2015 | 08Apr2015 |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 09Apr2015 | 23Apr2015 |
| DUMMY1 | 1mg(QD)  ORAL  TABLET | 24Apr2015 | 01May2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 02May2015 | 07May2015 |
| DUMMY1 | 3mg(QD)  ORAL  TABLET | 08May2015 | 21May2015 |
| DUMMY1 | 3mg(QD)  ORAL  TABLET | 22May2015 | 28May2015 |
| 14570A | 14570A-GB004-S2978 |  | UNITED KINGDOM  Female  34Years  White | PLACEBO | 0mg(QD)  ORAL  TABLET | 10Apr2015 | 16Apr2015 | Gastrointestinal disorders | Constipation | Expected  Non-serious  No | Recovered/Resolved | 17May2015 | Possibly Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 17Apr2015 | 20Apr2015 | Gastrointestinal disorders | Nausea | Unexpected  Non-serious  No | Recovered/Resolved | 18May2015 | Possibly Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 21Apr2015 | 07May2015 | Nervous system disorders | Dizziness | Expected  Non-serious  No | Recovered/Resolved | 18May2015 | Possibly Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 08May2015 | 21May2015 | General disorders and administration site conditions | Influenza like illness | Unexpected  Non-serious  No | Recovered/Resolved | 22May2015 | Possibly Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 22May2015 | 04Jun2015 | Respiratory, thoracic and mediastinal disorders | Oropharyngeal pain | Unexpected  Non-serious  No | Recovered/Resolved | 25May2015 | Possibly Related |
| DUMMY2 | 1mg(QD)  ORAL  TABLET | 05Jun2015 | 12Jun2015 | Psychiatric disorders | Abnormal dreams | Unexpected  Non-serious  No | Recovered/Resolved | 27May2015 | Possibly Related |
| DUMMY2 | 2mg(QD)  ORAL  TABLET | 13Jun2015 | 16Jun2015 | Nervous system disorders | Facial nerve disorder | Unexpected  Non-serious  No | Recovered/Resolved | 30May2015 | Possibly Related |
| DUMMY2 | 2mg(QD)  ORAL  TABLET | 17Jun2015 | 02Jul2015 | Investigations | Weight increased | Expected  Non-serious  Yes | Not Recovered/Not Resolved | 13Aug2015 | Related |
| DUMMY2 | 2mg(QD)  ORAL  TABLET | 03Jul2015 | 16Jul2015 | Cardiac disorders | Atrioventricular block first degree | Unexpected  Non-serious  No | Not Recovered/Not Resolved | 17Aug2015 | Possibly Related |
| DUMMY2 | 2mg(QD)  ORAL  TABLET | 17Jul2015 | 03Aug2015 | Psychiatric disorders | Depression | Unexpected  Non-serious  No | Recovering/Resolving | 13Nov2015 | Not Related |
| DUMMY2 | 2mg(QD)  ORAL  TABLET | 04Aug2015 | 13Aug2015 |
| DUMMY2 | 2mg(QD)  ORAL  TABLET | 14Aug2015 | 29Aug2015 |
| 14570A | 14570A-MX008-S3275 |  | MEXICO  Male  41Years  White | PLACEBO | 0mg(QD)  ORAL  TABLET | 07Jul2015 | 14Jul2015 | Musculoskeletal and connective tissue disorders | Back pain | Expected  Non-serious  No | Not Recovered/Not Resolved | 20Jul2015 | Not Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 15Jul2015 | 20Jul2015 | Musculoskeletal and connective tissue disorders | Neck pain | Unexpected  Non-serious  No | Not Recovered/Not Resolved | 20Jul2015 | Not Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 22Jul2015 | 03Aug2015 | Nervous system disorders | Akathisia | Expected  Non-serious  Yes | Not Recovered/Not Resolved | 20Oct2015 | Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 04Aug2015 | 17Aug2015 |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 18Aug2015 | 31Aug2015 |
| DUMMY1 | 1mg(QD)  ORAL  TABLET | 01Sep2015 | 08Sep2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 09Sep2015 | 11Sep2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 11Sep2015 | 28Sep2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 29Sep2015 | 12Oct2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 12Oct2015 | 26Oct2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 27Oct2015 | 08Nov2015 |
| 14570A | 14570A-PL002-S2654 |  | POLAND  Female  45Years  White | PLACEBO | 0mg(QD)  ORAL  TABLET | 30Jan2015 | 03Feb2015 | General disorders and administration site conditions | Asthenia | Unexpected  Non-serious  No | Recovering/Resolving | 29Apr2015 | Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 04Feb2015 | 13Feb2015 | Nervous system disorders | Hypoaesthesia | Unexpected  Non-serious  No | Recovered/Resolved | 24May2015 | Possibly Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 14Feb2015 | 26Feb2015 | Nervous system disorders | Akathisia | Expected  Non-serious  No | Recovering/Resolving | 24May2015 | Possibly Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 27Feb2015 | 12Mar2015 | Psychiatric disorders | Depression | Unexpected  Non-serious  Yes | Recovered/Resolved | 24Jun2015 | Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 13Mar2015 | 27Mar2015 |
| DUMMY2 | 1mg(QD)  ORAL  TABLET | 28Mar2015 | 04Apr2015 |
| DUMMY2 | 2mg(QD)  ORAL  TABLET | 05Apr2015 | 09Apr2015 |
| DUMMY2 | 3mg(QD)  ORAL  TABLET | 10Apr2015 | 23Apr2015 |
| DUMMY2 | 3mg(QD)  ORAL  TABLET | 24Apr2015 | 07May2015 |
| DUMMY2 | 3mg(QD)  ORAL  TABLET | 08May2015 | 21May2015 |
| DUMMY2 | 3mg(QD)  ORAL  TABLET | 22May2015 | 05Jun2015 |
| DUMMY2 | 3mg(QD)  ORAL  TABLET | 06Jun2015 | 29Jun2015 |
| 14570A | 14570A-PL002-S3481 |  | POLAND  Male  58Years  White | PLACEBO | 0mg(QD)  ORAL  TABLET | 25Sep2015 | 02Oct2015 | Nervous system disorders | Ruptured cerebral aneurysm | Unexpected  Serious  Yes | Recovered/Resolved with Sequelae | 07Jan2016 | Not Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 03Oct2015 | 08Oct2015 |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 09Oct2015 | 22Oct2015 |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 23Oct2015 | 05Nov2015 |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 06Nov2015 | 19Nov2015 |
| DUMMY1 | 1mg(QD)  ORAL  TABLET | 20Nov2015 | 27Nov2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 28Nov2015 | 03Dec2015 |
| DUMMY1 | 3mg(QD)  ORAL  TABLET | 04Dec2015 | 17Dec2015 |
| DUMMY1 | 3mg(QD)  ORAL  TABLET | 18Dec2015 | 30Dec2015 |
| DUMMY1 | 3mg(QD)  ORAL  TABLET | 31Dec2015 | 07Jan2016 |
| 14570A | 14570A-PL016-S3075 |  | POLAND  Female  28Years  White | PLACEBO | 0mg(QD)  ORAL  TABLET | 05May2015 | 13May2015 | Injury, poisoning and procedural complications | Intentional overdose | Unexpected  Serious  Yes | Recovered/Resolved | 05Jul2015 | Not Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 14May2015 | 19May2015 | Nervous system disorders | Intercostal neuralgia | Unexpected  Non-serious  No | Recovered/Resolved | 13Jun2015 | Not Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 20May2015 | 03Jun2015 | Psychiatric disorders | Insomnia | Expected  Non-serious  No | Recovered/Resolved | 06Jul2015 | Not Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 04Jun2015 | 17Jun2015 | Psychiatric disorders | Insomnia | Expected  Non-serious  No | Recovered/Resolved | 04Aug2015 | Not Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 18Jun2015 | 26Jun2015 |
| DUMMY1 | 1mg(QD)  ORAL  TABLET | 27Jun2015 | 04Jul2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 05Jul2015 | 10Jul2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 11Jul2015 | 27Jul2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 28Jul2015 | 11Aug2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 12Aug2015 | 25Aug2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 26Aug2015 | 07Sep2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 08Sep2015 | 23Sep2015 |
| 14570A | 14570A-PL019-S2894 |  | POLAND  Female  57Years  White | PLACEBO | 0mg(QD)  ORAL  TABLET | 19Mar2015 | 26Mar2015 | Investigations | Weight decreased | Unexpected  Non-serious  No | Not Recovered/Not Resolved | 12Jun2015 | Possibly Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 27Mar2015 | 31Mar2015 | Gastrointestinal disorders | Toothache | Unexpected  Non-serious  No | Recovered/Resolved | 28Jun2015 | Not Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 01Apr2015 | 16Apr2015 | Gastrointestinal disorders | Diarrhoea | Unexpected  Non-serious  No | Recovered/Resolved | 10Jul2015 | Possibly Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 17Apr2015 | 28Apr2015 | Investigations | Alanine aminotransferase increased | Unexpected  Non-serious  Yes | Not Recovered/Not Resolved | 23Jul2015 | Possibly Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 29Apr2015 | 13May2015 | Investigations | Aspartate aminotransferase increased | Unexpected  Non-serious  Yes | Not Recovered/Not Resolved | 23Jul2015 | Possibly Related |
| DUMMY2 | 1mg(QD)  ORAL  TABLET | 14May2015 | 21May2015 | Investigations | Gamma-glutamyltransferase increased | Unexpected  Non-serious  Yes | Not Recovered/Not Resolved | 23Jul2015 | Possibly Related |
| DUMMY2 | 2mg(QD)  ORAL  TABLET | 22May2015 | 28May2015 |
| DUMMY2 | 2mg(QD)  ORAL  TABLET | 29May2015 | 11Jun2015 |
| DUMMY2 | 1mg(QD)  ORAL  TABLET | 12Jun2015 | 24Jun2015 |
| DUMMY2 | 1mg(QD)  ORAL  TABLET | 25Jun2015 | 09Jul2015 |
| DUMMY2 | 1mg(QD)  ORAL  TABLET | 10Jul2015 | 23Jul2015 |
| DUMMY2 | 1mg(QD)  ORAL  TABLET | 24Jul2015 | 29Jul2015 |
| 14570A | 14570A-UA012-S3402 |  | UKRAINE  Female  56Years  White | PLACEBO | 0mg(QD)  ORAL  TABLET | 27Aug2015 | 02Sep2015 | Investigations | Electrocardiogram QT prolonged | Unexpected  Non-serious  Yes | Not Recovered/Not Resolved | 07Oct2015 | Possibly Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 03Sep2015 | 09Sep2015 |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 10Sep2015 | 23Sep2015 |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 24Sep2015 | 07Oct2015 |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 08Oct2015 | 21Oct2015 |
| DUMMY2 | 1mg(QD)  ORAL  TABLET | 22Oct2015 | 29Oct2015 |
| DUMMY2 | 2mg(QD)  ORAL  TABLET | 30Oct2015 | 04Nov2015 |
| DUMMY2 | 2mg(QD)  ORAL  TABLET | 05Nov2015 | 09Nov2015 |
| 14570A | 14570A-US041-S3073 |  | UNITED STATES  Female  59Years  White | PLACEBO | 0mg(QD)  ORAL  TABLET | 29Apr2015 | 08May2015 | Musculoskeletal and connective tissue disorders | Fibromyalgia | Unexpected  Non-serious  No | Recovering/Resolving | 03Jun2015 | Not Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 09May2015 | 13May2015 | Investigations | Blood glucose increased | Unexpected  Non-serious  Yes | Not Recovered/Not Resolved | 09Jun2015 | Not Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 13May2015 | 26May2015 | Investigations | Weight increased | Expected  Non-serious  Yes | Not Recovered/Not Resolved | 23Jun2015 | Related |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 27May2015 | 09Jun2015 |
| PLACEBO | 0mg(QD)  ORAL  TABLET | 10Jun2015 | 22Jun2015 |
| DUMMY1 | 1mg(QD)  ORAL  TABLET | 23Jun2015 | 30Jun2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 01Jul2015 | 13Jul2015 |
| DUMMY1 | 2mg(QD)  ORAL  TABLET | 14Jul2015 | 20Jul2015 |
| DUMMY1 | 3mg(QD)  ORAL  TABLET | 21Jul2015 | 04Aug2015 |
| 14644B | 14644A-RU013-S1536 |  | RUSSIAN FEDERATION  Male  46Years  White | BREXPIPRAZOLE | 2mg(QD)  ORAL  TABLET | 16Sep2014 | 21Sep2014 | Psychiatric disorders | Schizophrenia | Unexpected  Serious  Yes | Recovered/Resolved | 14Jun2015 | Possibly Related |
| BREXPIPRAZOLE | 3mg(QD)  ORAL  TABLET | 22Sep2014 | 29Sep2014 |
| BREXPIPRAZOLE | 3mg(QD)  ORAL  TABLET | 30Sep2014 | 18Oct2014 |
| BREXPIPRAZOLE | 4mg(QD)  ORAL  TABLET | 19Oct2014 | 10Nov2014 |
| BREXPIPRAZOLE | 4mg(QD)  ORAL  TABLET | 11Nov2014 | 22Dec2014 |
| BREXPIPRAZOLE | 4mg(QD)  ORAL  TABLET | 23Dec2014 | 02Feb2015 |
| BREXPIPRAZOLE | 4mg(QD)  ORAL  TABLET | 03Feb2015 | 20Mar2015 |
| BREXPIPRAZOLE | 4mg(QD)  ORAL  TABLET | 21Mar2015 | 28Apr2015 |
| BREXPIPRAZOLE | 4mg(QD)  ORAL  TABLET | 29Apr2015 | 14Jun2015 |
| 14644B | 14644A-RU015-S1655 |  | RUSSIAN FEDERATION  Female  61Years  White | BREXPIPRAZOLE | 2mg(QD)  ORAL  TABLET | 11Nov2014 | 17Nov2014 | Investigations | Blood creatinine increased | Unexpected  Non-serious  Yes | Recovered/Resolved | 27Apr2015 | Possibly Related |
| BREXPIPRAZOLE | 3mg(QD)  ORAL  TABLET | 18Nov2014 | 24Nov2014 |
| BREXPIPRAZOLE | 4mg(QD)  ORAL  TABLET | 25Nov2014 | 09Dec2014 |
| BREXPIPRAZOLE | 4mg(QD)  ORAL  TABLET | 10Dec2014 | 29Dec2014 |
| BREXPIPRAZOLE | 4mg(QD)  ORAL  TABLET | 30Dec2014 | 09Feb2015 |
| BREXPIPRAZOLE | 4mg(QD)  ORAL  TABLET | 10Feb2015 | 23Mar2015 |
| BREXPIPRAZOLE | 4mg(QD)  ORAL  TABLET | 24Mar2015 | 27Apr2015 |
| BREXPIPRAZOLE | 4mg(QD)  ORAL  TABLET | 28Apr2015 | 18Jun2015 |
| BREXPIPRAZOLE | 4mg(QD)  ORAL  TABLET | 19Jun2015 | 23Jul2015 |
| BREXPIPRAZOLE | 4mg(QD)  ORAL  TABLET | 24Jul2015 | 14Sep2015 |
| BREXPIPRAZOLE | 4mg(QD)  ORAL  TABLET | 15Sep2015 | 08Nov2015 |
| 14644B | 14644A-UA002-S1506 |  | UKRAINE  Female  39Years  White | BREXPIPRAZOLE | 2mg(QD)  ORAL  TABLET | 22Aug2014 | 26Aug2014 | Pregnancy, puerperium and perinatal conditions | Pregnancy | Unexpected  Serious  Yes | Recovered/Resolved | 13May2015 | Not Related |
| BREXPIPRAZOLE | 3mg(QD)  ORAL  TABLET | 27Aug2014 | 03Sep2014 | Reproductive system and breast disorders | Ovarian cyst | Unexpected  Non-serious  No | Not Recovered/Not Resolved | 13May2015 | Possibly Related |
| BREXPIPRAZOLE | 4mg(QD)  ORAL  TABLET | 04Sep2014 | 17Sep2014 |
| BREXPIPRAZOLE | 4mg(QD)  ORAL  TABLET | 18Sep2014 | 16Oct2014 |
| BREXPIPRAZOLE | 4mg(QD)  ORAL  TABLET | 17Oct2014 | 01Dec2014 |
| BREXPIPRAZOLE | 4mg(QD)  ORAL  TABLET | 02Dec2014 | 08Jan2015 |
| BREXPIPRAZOLE | 4mg(QD)  ORAL  TABLET | 09Jan2015 | 19Feb2015 |
| BREXPIPRAZOLE | 4mg(QD)  ORAL  TABLET | 20Feb2015 | 06Apr2015 |
| BREXPIPRAZOLE | 4mg(QD)  ORAL  TABLET | 07Apr2015 | 12May2015 |
| 14644B | 14644A-UA004-S1559 |  | UKRAINE  Male  38Years  White | BREXPIPRAZOLE | 2mg(QD)  ORAL  TABLET | 26Sep2014 | 01Oct2014 | Psychiatric disorders | Schizophrenia | Unexpected  Serious  Yes | Not Recovered/Not Resolved | 12Aug2015 | Possibly Related |
| BREXPIPRAZOLE | 3mg(QD)  ORAL  TABLET | 02Oct2014 | 08Oct2014 |
| BREXPIPRAZOLE | 4mg(QD)  ORAL  TABLET | 09Oct2014 | 23Oct2014 |
| BREXPIPRAZOLE | 4mg(QD)  ORAL  TABLET | 24Oct2014 | 20Nov2014 |
| BREXPIPRAZOLE | 4mg(QD)  ORAL  TABLET | 21Nov2014 | 06Jan2015 |
| BREXPIPRAZOLE | 4mg(QD)  ORAL  TABLET | 07Jan2015 | 11Feb2015 |
| BREXPIPRAZOLE | 3mg(QD)  ORAL  TABLET | 12Feb2015 | 26Mar2015 |
| BREXPIPRAZOLE | 3mg(QD)  ORAL  TABLET | 27Mar2015 | 07May2015 |
| BREXPIPRAZOLE | 3mg(QD)  ORAL  TABLET | 08May2015 | 18Jun2015 |
| BREXPIPRAZOLE | 3mg(QD)  ORAL  TABLET | 19Jun2015 | 30Jul2015 |
| BREXPIPRAZOLE | 3mg(QD)  ORAL  TABLET | 31Jul2015 | 19Aug2015 |
| 14644B | 14644A-UA004-S1620 |  | UKRAINE  Female  47Years  White | BREXPIPRAZOLE | 2mg(QD)  ORAL  TABLET | 23Oct2014 | 28Oct2014 | Psychiatric disorders | Schizophrenia | Unexpected  Serious  Yes | Not Recovered/Not Resolved | 02Oct2015 | Possibly Related |
| BREXPIPRAZOLE | 3mg(QD)  ORAL  TABLET | 29Oct2014 | 04Nov2014 |
| BREXPIPRAZOLE | 4mg(QD)  ORAL  TABLET | 05Nov2014 | 19Nov2014 |
| BREXPIPRAZOLE | 4mg(QD)  ORAL  TABLET | 20Nov2014 | 17Dec2014 |
| BREXPIPRAZOLE | 4mg(QD)  ORAL  TABLET | 18Dec2014 | 28Jan2015 |
| BREXPIPRAZOLE | 4mg(QD)  ORAL  TABLET | 29Jan2015 | 10Mar2015 |
| BREXPIPRAZOLE | 3mg(QD)  ORAL  TABLET | 11Mar2015 | 21Apr2015 |
| BREXPIPRAZOLE | 4mg(QD)  ORAL  TABLET | 22Apr2015 | 02Jun2015 |
| BREXPIPRAZOLE | 3mg(QD)  ORAL  TABLET | 03Jun2015 | 15Jul2015 |
| BREXPIPRAZOLE | 3mg(QD)  ORAL  TABLET | 16Jul2015 | 25Aug2015 |
| BREXPIPRAZOLE | 4mg(QD)  ORAL  TABLET | 26Aug2015 | 02Oct2015 |
| 14644B | 14644A-UA009-S1676 |  | UKRAINE  Male  58Years  Other | BREXPIPRAZOLE | 2mg(QD)  ORAL  TABLET | 12Nov2014 | 18Nov2014 | Psychiatric disorders | Schizophrenia | Unexpected  Serious  Yes | Recovered/Resolved | 06Jul2015 | Not Related |
| BREXPIPRAZOLE | 3mg(QD)  ORAL  TABLET | 19Nov2014 | 25Nov2014 | Investigations | Weight increased | Expected  Non-serious  No | Not Recovered/Not Resolved | 13May2015 | Possibly Related |
| BREXPIPRAZOLE | 3mg(QD)  ORAL  TABLET | 26Nov2014 | 10Dec2014 |
| BREXPIPRAZOLE | 4mg(QD)  ORAL  TABLET | 11Dec2014 | 16Dec2014 |
| BREXPIPRAZOLE | 3mg(QD)  ORAL  TABLET | 17Dec2014 | 23Dec2014 |
| BREXPIPRAZOLE | 2mg(QD)  ORAL  TABLET | 24Dec2014 | 13Jan2015 |
| BREXPIPRAZOLE | 2mg(QD)  ORAL  TABLET | 14Jan2015 | 17Feb2015 |
| BREXPIPRAZOLE | 3mg(QD)  ORAL  TABLET | 18Feb2015 | 31Mar2015 |
| BREXPIPRAZOLE | 3mg(QD)  ORAL  TABLET | 01Apr2015 | 13May2015 |
| BREXPIPRAZOLE | 3mg(QD)  ORAL  TABLET | 14May2015 | 23Jun2015 |
| BREXPIPRAZOLE | 4mg(QD)  ORAL  TABLET | 24Jun2015 | 09Jul2015 |
| 331-10-002 | 005-1010 |  | JAPAN  Male  24Years  Asian | OPC-34712 1MG | 1mg(DAY)  ORAL  TABLET | 23Apr2015 | 26Apr2015 | Psychiatric disorders | Schizophrenia | Unexpected  Non-serious  Yes | Recovered/Resolved | 10May2015 | Unrelated |
| OPC-34712 1MG | 1mg(DAY)  ORAL  TABLET | 27Apr2015 | 29Apr2015 |
| OPC-34712 1MG | 1mg(DAY)  ORAL  TABLET | 30Apr2015 | 06May2015 |
| OPC-34712 1MG | 1mg(DAY)  ORAL  TABLET | 07May2015 | 12May2015 |
| OPC-34712 1MG | 1mg(DAY)  ORAL  TABLET | 13May2015 | 13May2015 |
| 331-10-002 | 062-1046 |  | JAPAN  Male  51Years  Asian | OPC-34712 2MG | 1mg(DAY)  ORAL  TABLET | 30Apr2015 | 03May2015 | Infections and infestations | Conjunctivitis | Unexpected  Non-serious  No | Recovered/Resolved | 03May2015 | Unrelated |
| OPC-34712 2MG | 2mg(DAY)  ORAL  TABLET | 04May2015 | 06May2015 | Psychiatric disorders | Schizophrenia | Unexpected  Non-serious  Yes | Recovered/Resolved | 19May2015 | Unrelated |
| OPC-34712 2MG | 2mg(DAY)  ORAL  TABLET | 07May2015 | 13May2015 |
| OPC-34712 2MG | 2mg(DAY)  ORAL  TABLET | 14May2015 | 20May2015 |
| OPC-34712 2MG | 2mg(DAY)  ORAL  TABLET | 21May2015 | 27May2015 |
| OPC-34712 2MG | 2mg(DAY)  ORAL  TABLET | 28May2015 | 03Jun2015 |
| OPC-34712 2MG | 2mg(DAY)  ORAL  TABLET | 04Jun2015 | 05Jun2015 |
| 331-10-002 | 069-1003 |  | JAPAN  Female  57Years  Asian | OPC-34712 4MG | 1mg(DAY)  ORAL  TABLET | 20Mar2015 | 23Mar2015 | Nervous system disorders | Psychomotor hyperactivity | Unexpected  Non-serious  Yes | Recovered/Resolved | 21Apr2015 | Unrelated |
| OPC-34712 4MG | 2mg(DAY)  ORAL  TABLET | 24Mar2015 | 26Mar2015 | Gastrointestinal disorders | Vomiting | Unexpected  Non-serious  No | Recovered/Resolved | 29Apr2015 | Unrelated |
| OPC-34712 4MG | 4mg(DAY)  ORAL  TABLET | 27Mar2015 | 02Apr2015 | Nervous system disorders | Dizziness | Expected  Non-serious  No | Recovered/Resolved | 22May2015 | Unrelated |
| OPC-34712 4MG | 4mg(DAY)  ORAL  TABLET | 03Apr2015 | 08Apr2015 |
| OPC-34712 4MG | 4mg(DAY)  ORAL  TABLET | 09Apr2015 | 16Apr2015 |
| OPC-34712 4MG | 4mg(DAY)  ORAL  TABLET | 17Apr2015 | 20Apr2015 |
| 331-10-002 | 105-1011 |  | JAPAN  Male  33Years  Asian | OPC-34712 1MG | 1mg(DAY)  ORAL  TABLET | 22Apr2015 | 25Apr2015 | Psychiatric disorders | Schizophrenia | Unexpected  Serious  Yes | Recovered/Resolved | 26Apr2015 | Unrelated |
| OPC-34712 1MG | 1mg(DAY)  ORAL  TABLET | 26Apr2015 | 27Apr2015 |
| OPC-34712 1MG | 1mg(DAY)  ORAL  TABLET | 28Apr2015 | 28Apr2015 |
| OPC-34712 1MG | 1mg(DAY)  ORAL  TABLET | 29Apr2015 | 30Apr2015 |
| 331-10-233 | 006-S0611 |  | UNITED STATES  Male  15Years  Black or African American | COHORT 2 1 MG | ORAL  TABLET | 30Sep2015 | 30Sep2015 | Psychiatric disorders | Anxiety | Expected  Non-serious  No | Recovered/Resolved | 01Oct2015 | Not Related |
| COHORT 2 1 MG | ORAL  TABLET | 01Oct2015 | 01Oct2015 | Psychiatric disorders | Agitation | Expected  Non-serious  No | Recovered/Resolved | 01Oct2015 | Not Related |
| COHORT 2 1 MG | ORAL  TABLET | 02Oct2015 | 02Oct2015 | Psychiatric disorders | Insomnia | Expected  Non-serious  No | Recovered/Resolved | 01Oct2015 | Not Related |
| COHORT 2 1 MG | ORAL  TABLET | 03Oct2015 | 03Oct2015 | Psychiatric disorders | Paranoia | Unexpected  Non-serious  No | Recovered/Resolved | 08Oct2015 | Not Related |
| COHORT 2 1 MG | ORAL  TABLET | 04Oct2015 | 04Oct2015 | Psychiatric disorders | Schizophrenia | Unexpected  Non-serious  Yes | Recovered/Resolved | 08Oct2015 | Not Related |
| COHORT 2 1 MG | ORAL  TABLET | 05Oct2015 | 05Oct2015 |
| COHORT 2 1 MG | ORAL  TABLET | 06Oct2015 | 06Oct2015 |
| COHORT 2 1 MG | ORAL  TABLET | 07Oct2015 | 07Oct2015 |
| 331-10-237 | 960-S8692 |  | UKRAINE  Female  40Years  White | PRIOR OPC | PO  TABLET | 19Dec2014 | 24Dec2014 | Psychiatric disorders | Schizophrenia | Unexpected  Serious  Yes | Recovered/Resolved | 07Jun2015 | Not Related |
| PRIOR OPC | PO  TABLET | 25Dec2014 | 30Dec2014 | Psychiatric disorders | Schizophrenia | Unexpected  Non-serious  No | Recovered/Resolved | 05Jun2015 | Not Related |
| PRIOR OPC | PO  TABLET | 31Dec2014 | 14Jan2015 |
| PRIOR OPC | PO  TABLET | 15Jan2015 | 11Feb2015 |
| PRIOR OPC | PO  TABLET | 12Feb2015 | 25Mar2015 |
| PRIOR OPC | PO  TABLET | 26Mar2015 | 05May2015 |
| PRIOR OPC | PO  TABLET | 06May2015 | 07Jun2015 |
| PRIOR OPC | PO  TABLET | 08Jun2015 | 10Jun2015 |
| 331-10-237 | 986-S8582 |  | COLOMBIA  Male  22Years  White | PRIOR OPC | PO  TABLET | 23Dec2014 | 23Dec2014 | Psychiatric disorders | Schizophrenia | Unexpected  Serious  Yes | Recovered/Resolved | 19Oct2015 | Not Related |
| PRIOR OPC | PO  TABLET | 24Dec2014 | 24Dec2014 | Psychiatric disorders | Schizophrenia | Unexpected  Non-serious  No | Recovered/Resolved | 16Oct2015 | Not Related |
| PRIOR OPC | PO  TABLET | 25Dec2014 | 29Dec2014 | Eye disorders | Ocular hyperaemia | Unexpected  Non-serious  No | Recovered/Resolved | 23Oct2015 | Not Related |
| PRIOR OPC | PO  TABLET | 30Dec2014 | 07Jan2015 | Nervous system disorders | Headache | Unexpected  Non-serious  No | Recovered/Resolved | 29Oct2015 | Not Related |
| PRIOR OPC | PO  TABLET | 08Jan2015 | 19Jan2015 |
| PRIOR OPC | PO  TABLET | 20Jan2015 | 16Feb2015 |
| PRIOR OPC | PO  TABLET | 17Feb2015 | 30Mar2015 |
| PRIOR OPC | PO  TABLET | 31Mar2015 | 08May2015 |
| PRIOR OPC | PO  TABLET | 09May2015 | 04Jun2015 |
| PRIOR OPC | PO  TABLET | 05Jun2015 | 05Jun2015 |
| PRIOR OPC | PO  TABLET | 06Jun2015 | 09Jun2015 |
| PRIOR OPC | PO  TABLET | 10Jun2015 | 10Jun2015 |
| PRIOR OPC | PO  TABLET | 11Jun2015 | 14Jun2015 |
| PRIOR OPC | PO  TABLET | 15Jun2015 | 15Jun2015 |
| PRIOR OPC | PO  TABLET | 16Jun2015 | 22Jun2015 |
| PRIOR OPC | PO  TABLET | 23Jun2015 | 03Aug2015 |
| PRIOR OPC | PO  TABLET | 04Aug2015 | 14Sep2015 |
| PRIOR OPC | PO  TABLET | 15Sep2015 | 19Oct2015 |
| 331-10-237 | 986-S8590 |  | COLOMBIA  Male  23Years  Other | PRIOR OPC | PO  TABLET | 30Dec2014 | 05Jan2015 | Psychiatric disorders | Schizophrenia | Unexpected  Serious  Yes | Recovered/Resolved | 24Sep2015 | Possibly Related |
| PRIOR OPC | PO  TABLET | 06Jan2015 | 13Jan2015 | Psychiatric disorders | Schizophrenia | Unexpected  Non-serious  No | Recovered/Resolved | 18Sep2015 | Possibly Related |
| PRIOR OPC | PO  TABLET | 14Jan2015 | 26Jan2015 |
| PRIOR OPC | PO  TABLET | 27Jan2015 | 23Feb2015 |
| PRIOR OPC | PO  TABLET | 24Feb2015 | 31Mar2015 |
| PRIOR OPC | PO  TABLET | 01Apr2015 | 02Apr2015 |
| PRIOR OPC | PO  TABLET | 03Apr2015 | 06Apr2015 |
| PRIOR OPC | PO  TABLET | 07Apr2015 | 20May2015 |
| PRIOR OPC | PO  TABLET | 21May2015 | 30Jun2015 |
| PRIOR OPC | PO  TABLET | 01Jul2015 | 10Aug2015 |
| PRIOR OPC | PO  TABLET | 11Aug2015 | 23Sep2015 |
| 331-10-237 | 986-S8595 |  | COLOMBIA  Male  31Years  Other | PRIOR OPC | PO  TABLET | 30Dec2014 | 05Jan2015 | Psychiatric disorders | Schizophrenia | Unexpected  Serious  Yes | Recovered/Resolved | 10Aug2015 | Not Related |
| PRIOR OPC | PO  TABLET | 06Jan2015 | 11Jan2015 |
| PRIOR OPC | PO  TABLET | 12Jan2015 | 12Jan2015 |
| PRIOR OPC | PO  TABLET | 13Jan2015 | 13Jan2015 |
| PRIOR OPC | PO  TABLET | 14Jan2015 | 26Jan2015 |
| PRIOR OPC | PO  TABLET | 27Jan2015 | 23Feb2015 |
| PRIOR OPC | PO  TABLET | 24Feb2015 | 08Apr2015 |
| PRIOR OPC | PO  TABLET | 09Apr2015 | 21May2015 |
| PRIOR OPC | PO  TABLET | 22May2015 | 28Jun2015 |
| PRIOR OPC | PO  TABLET | 29Jun2015 | 30Jun2015 |
| PRIOR OPC | PO  TABLET | 01Jul2015 | 02Jul2015 |
| PRIOR OPC | PO  TABLET | 03Jul2015 | 10Aug2015 |
| 331-10-237 | 987-S8649 |  | COLOMBIA  Male  38Years  Other | PRIOR OPC | PO  TABLET | 30Dec2014 | 06Jan2015 | Psychiatric disorders | Schizophrenia | Unexpected  Serious  Yes | Recovered/Resolved | 06Aug2015 | Not Related |
| PRIOR OPC | PO  TABLET | 07Jan2015 | 13Jan2015 | Gastrointestinal disorders | Constipation | Expected  Non-serious  No | Recovered/Resolved | 15Aug2015 | Not Related |
| PRIOR OPC | PO  TABLET | 14Jan2015 | 27Jan2015 |
| PRIOR OPC | PO  TABLET | 28Jan2015 | 23Feb2015 |
| PRIOR OPC | PO  TABLET | 24Feb2015 | 06Apr2015 |
| PRIOR OPC | PO  TABLET | 07Apr2015 | 19May2015 |
| PRIOR OPC | PO  TABLET | 20May2015 | 30Jun2015 |
| PRIOR OPC | PO  TABLET | 01Jul2015 | 10Aug2015 |
| 331-10-237 | 987-S8734 |  | COLOMBIA  Female  32Years  Other | PRIOR OPC | PO  TABLET | 19Dec2014 | 22Dec2014 | Psychiatric disorders | Schizophrenia | Unexpected  Serious  Yes | Recovered/Resolved | 16Dec2015 | Not Related |
| PRIOR OPC | PO  TABLET | 23Dec2014 | 30Dec2014 | Psychiatric disorders | Insomnia | Expected  Non-serious  No | Recovered/Resolved | 10Jun2015 | Not Related |
| PRIOR OPC | PO  TABLET | 31Dec2014 | 14Jan2015 | Psychiatric disorders | Schizophrenia | Unexpected  Non-serious  No | Recovered/Resolved | 13Dec2015 | Not Related |
| PRIOR OPC | PO  TABLET | 15Jan2015 | 10Feb2015 | Infections and infestations | Gingivitis | Unexpected  Non-serious  No | Recovered/Resolved | 19Dec2015 | Not Related |
| PRIOR OPC | PO  TABLET | 11Feb2015 | 24Mar2015 |
| PRIOR OPC | PO  TABLET | 25Mar2015 | 06May2015 |
| PRIOR OPC | PO  TABLET | 07May2015 | 17Jun2015 |
| PRIOR OPC | PO  TABLET | 18Jun2015 | 29Jul2015 |
| PRIOR OPC | PO  TABLET | 30Jul2015 | 08Sep2015 |
| PRIOR OPC | PO  TABLET | 09Sep2015 | 20Oct2015 |
| PRIOR OPC | PO  TABLET | 21Oct2015 | 03Dec2015 |
| PRIOR OPC | PO  TABLET | 04Dec2015 | 15Dec2015 |
| PRIOR OPC | PO  TABLET | 16Dec2015 | 16Dec2015 |
| 331-10-238 | 006-S8305 |  | UNITED STATES  Female  51Years  Native Hawaiian or Other Pacific Islander | PRIOR ADT | PO  TABLET | 04Nov2015 | 08Nov2015 | Investigations | Weight increased | Expected  Non-serious  Yes | Recovered/Resolved | 28Dec2015 | Possibly Related |
| PRIOR ADT | PO  TABLET | 04Nov2015 | 27Dec2015 |
| PRIOR ADT | PO  TABLET | 09Nov2015 | 10Nov2015 |
| PRIOR ADT | PO  TABLET | 11Nov2015 | 11Nov2015 |
| PRIOR ADT | PO  TABLET | 12Nov2015 | 27Dec2015 |
| 331-10-238 | 322-S8312 |  | UNITED STATES  Female  52Years  White | PRIOR ADT | 0mg(DAY)  PO  TABLET | 23Nov2015 | 28Nov2015 | Nervous system disorders | Migraine | Unexpected  Non-serious  Yes | Recovered/Resolved | 23Dec2015 | Related |
| PRIOR ADT | 0mg(DAY)  PO  TABLET | 29Nov2015 | 29Nov2015 | Nervous system disorders | Migraine | Unexpected  Non-serious  No | Not Recovered/Not Resolved | 09Feb2016 | Possibly Related |
| PRIOR ADT | PO  TABLET | 30Nov2015 | 01Dec2015 |
| PRIOR ADT | PO  TABLET | 30Nov2015 | 20Dec2015 |
| PRIOR ADT | PO  TABLET | 02Dec2015 | 08Dec2015 |
| PRIOR ADT | PO  TABLET | 09Dec2015 | 22Dec2015 |
| PRIOR ADT | PO  TABLET | 21Dec2015 | 21Dec2015 |
| PRIOR ADT | PO  TABLET | 22Dec2015 | 31Dec2015 |
| PRIOR ADT | PO  TABLET | 23Dec2015 | 27Dec2015 |
| PRIOR ADT | PO  TABLET | 28Dec2015 | 28Dec2015 |
| PRIOR ADT | PO  TABLET | 29Dec2015 | 31Dec2015 |
| PRIOR ADT | 0mg(DAY)  PO  TABLET | 01Jan2016 | 01Jan2016 |
| PRIOR ADT | 0mg(DAY)  PO  TABLET | 02Jan2016 | 10Jan2016 |
| PRIOR ADT | 0mg(DAY)  PO  TABLET | 11Jan2016 | 11Jan2016 |
| PRIOR ADT | 0mg(DAY)  PO  TABLET | 12Jan2016 | 23Dec2015 |
| 331-10-238 | 395-S7763 |  | GERMANY  Female  51Years  White | PRIOR PLACEBO | PO  TABLET | 12Mar2015 | 18Mar2015 | Psychiatric disorders | Depression | Unexpected  Serious  Yes | Not Recovered/Not Resolved | 30Jul2015 | Not Related |
| PRIOR PLACEBO | PO  TABLET | 12Mar2015 | 29Jul2015 |
| PRIOR PLACEBO | PO  TABLET | 19Mar2015 | 17Jun2015 |
| PRIOR PLACEBO | PO  TABLET | 18Jun2015 | 29Jul2015 |
| 331-10-238 | 418-S7999 |  | RUSSIAN FEDERATION  Female  54Years  White | PRIOR ADT | PO  TABLET | 24Jun2015 | 30Jun2015 | Musculoskeletal and connective tissue disorders | Muscular weakness | Unexpected  Non-serious  No | Recovered/Resolved | 09Jul2015 | Possibly Related |
| PRIOR ADT | PO  TABLET | 24Jun2015 | 01Oct2015 | Nervous system disorders | Tremor | Expected  Non-serious  No | Recovered/Resolved | 29Aug2015 | Possibly Related |
| PRIOR ADT | PO  TABLET | 01Jul2015 | 21Jul2015 | Psychiatric disorders | Anxiety | Expected  Non-serious  Yes | Recovered/Resolved | 17Oct2015 | Unlikely Related |
| PRIOR ADT | PO  TABLET | 22Jul2015 | 20Aug2015 |
| PRIOR ADT | PO  TABLET | 21Aug2015 | 01Oct2015 |
| PRIOR ADT | PO  TABLET | 02Oct2015 | 19Oct2015 |
| PRIOR ADT | PO  TABLET | 02Oct2015 | 17Dec2015 |
| PRIOR ADT | PO  TABLET | 20Oct2015 | 10Nov2015 |
| PRIOR ADT | PO  TABLET | 11Nov2015 | 17Dec2015 |
| 331-10-238 | 427-S8128 |  | RUSSIAN FEDERATION  Male  60Years  White | PRIOR PLACEBO | PO  TABLET | 19Aug2015 | 24Aug2015 | Investigations | Electrocardiogram QT prolonged | Unexpected  Non-serious  Yes | Not Recovered/Not Resolved | 19Aug2015 | Possibly Related |
| PRIOR PLACEBO | PO  TABLET | 19Aug2015 | 13Oct2015 | Nervous system disorders | Paraesthesia | Unexpected  Non-serious  No | Recovered/Resolved | 29Aug2015 | Not Related |
| PRIOR PLACEBO | PO  TABLET | 25Aug2015 | 13Oct2015 | General disorders and administration site conditions | Hyperthermia | Unexpected  Non-serious  No | Recovered/Resolved | 05Oct2015 | Not Related |
| Immune system disorders | Hypersensitivity | Expected  Non-serious  No | Recovered/Resolved | 22Oct2015 | Not Related |
| 331-10-238 | 766-S7805 |  | POLAND  Female  49Years  White | PRIOR ADT | PO  TABLET | 31Mar2015 | 08Apr2015 | Nervous system disorders | Somnolence | Expected  Non-serious  No | Recovered/Resolved | 20Apr2015 | Possibly Related |
| PRIOR ADT | PO  TABLET | 31Mar2015 | 05May2015 | Psychiatric disorders | Anxiety | Expected  Non-serious  Yes | Recovered/Resolved | 01May2015 | Possibly Related |
| PRIOR ADT | PO  TABLET | 09Apr2015 | 05May2015 |
| 331-10-238 | 796-S7861 |  | FRANCE  Male  47Years  White | PRIOR ADT | PO  TABLET | 13Apr2015 | 19Apr2015 | Psychiatric disorders | Suicide attempt | Unexpected  Serious  Yes | Recovered/Resolved | 30Jun2015 | Not Related |
| PRIOR ADT | PO  TABLET | 13Apr2015 | 05Jul2015 |
| PRIOR ADT | PO  TABLET | 20Apr2015 | 05Jul2015 |
| 331-10-238 | 796-S8000 |  | FRANCE  Female  41Years  White | PRIOR ADT | PO  TABLET | 25Jun2015 | 02Jul2015 | Vascular disorders | Hypotension | Unexpected  Non-serious  No | Recovered/Resolved | 27Jul2015 | Related |
| PRIOR ADT | PO  TABLET | 25Jun2015 | 24Jul2015 | Investigations | Weight increased | Expected  Non-serious  No | Recovered/Resolved | 27Jul2015 | Related |
| PRIOR ADT | PO  TABLET | 03Jul2015 | 20Aug2015 | Investigations | Weight increased | Expected  Non-serious  Yes | Recovered/Resolved | 07Sep2015 | Related |
| PRIOR ADT | PO  TABLET | 25Jul2015 | 26Jul2015 |
| PRIOR ADT | PO  TABLET | 27Jul2015 | 06Sep2015 |
| PRIOR ADT | PO  TABLET | 21Aug2015 | 06Sep2015 |
| 331-10-238 | 804-S7907 |  | Female  30Years  White | PRIOR ADT | PO  TABLET | 19May2015 | 27May2015 | Investigations | Weight increased | Expected  Non-serious  Yes | Not Recovered/Not Resolved | 18May2015 | Possibly Related |
| PRIOR ADT | PO  TABLET | 19May2015 | 26Aug2015 |
| PRIOR ADT | PO  TABLET | 28May2015 | 26Aug2015 |
| 331-10-238 | 808-S7902 |  | UNITED STATES  Female  28Years  White | PRIOR ADT | PO  TABLET | 13May2015 | 19May2015 | Nervous system disorders | Akathisia | Expected  Non-serious  Yes | Recovered/Resolved | 29May2015 | Related |
| PRIOR ADT | PO  TABLET | 14May2015 | 11Nov2015 | Infections and infestations | Upper respiratory tract infection | Unexpected  Non-serious  No | Recovered/Resolved | 08Jun2015 | Not Related |
| PRIOR ADT | PO  TABLET | 20May2015 | 31May2015 |
| PRIOR ADT | PO  TABLET | 01Jun2015 | 03Jun2015 |
| PRIOR ADT | PO  TABLET | 04Jun2015 | 08Jul2015 |
| PRIOR ADT | PO  TABLET | 09Jul2015 | 11Nov2015 |
| 331-10-238 | 819-S8073 |  | UNITED STATES  Female  27Years  White | PRIOR ADT | 0mg(DAY)  PO  TABLET | 20Jul2015 | 24Jul2015 | Musculoskeletal and connective tissue disorders | Back pain | Expected  Non-serious  No | Recovered/Resolved | 22Jul2015 | Unlikely Related |
| PRIOR ADT | 0mg(DAY)  PO  TABLET | 25Jul2015 | 25Jul2015 | Nervous system disorders | Somnolence | Expected  Non-serious  No | Recovered/Resolved | 22Jul2015 | Related |
| PRIOR ADT | PO  TABLET | 26Jul2015 | 26Jul2015 | Gastrointestinal disorders | Dry mouth | Expected  Non-serious  No | Recovered/Resolved | 23Jul2015 | Possibly Related |
| PRIOR ADT | PO  TABLET | 26Jul2015 | 15Aug2015 | Nervous system disorders | Somnolence | Expected  Non-serious  Yes | Recovered/Resolved | 08Aug2015 | Related |
| PRIOR ADT | PO  TABLET | 27Jul2015 | 15Aug2015 | Infections and infestations | Nasopharyngitis | Expected  Non-serious  No | Recovered/Resolved | 07Sep2015 | Not Related |
| PRIOR ADT | 0mg(DAY)  PO  TABLET | 16Aug2015 | 16Aug2015 | Ear and labyrinth disorders | Vertigo | Unexpected  Non-serious  No | Not Recovered/Not Resolved | 02Oct2015 | Related |
| PRIOR ADT | 0mg(DAY)  PO  TABLET | 17Aug2015 | 01Oct2015 | Respiratory, thoracic and mediastinal disorders | Cough | Unexpected  Non-serious  No | Not Recovered/Not Resolved | 04Oct2015 | Not Related |
| PRIOR ADT | 0mg(DAY)  PO  TABLET | 02Oct2015 | 07Oct2015 |
| 331-10-238 | 821-S7890 |  | UNITED STATES  Female  31Years  White | PRIOR ADT | PO  TABLET | 06May2015 | 12May2015 | Investigations | Hepatic enzyme increased | Unexpected  Non-serious  Yes | Recovered/Resolved | 06May2015 | Not Related |
| PRIOR ADT | PO  TABLET | 06May2015 | 01Jun2015 |
| PRIOR ADT | PO  TABLET | 13May2015 | 21May2015 |
| PRIOR ADT | PO  TABLET | 22May2015 | 01Jun2015 |
| 331-12-282 | 006-S8264 |  | UNITED STATES  Female  49Years  White |  |  |  |  | Gastrointestinal disorders | Nausea | Unexpected  Non-serious  No | Recovered/Resolved | 11Jun2015 | Unlikely Related |
| Gastrointestinal disorders | Vomiting | Unexpected  Non-serious  Yes | Recovered/Resolved | 11Jun2015 | Unlikely Related |
| 331-12-282 | 006-S8500 |  | UNITED STATES  Female  46Years  Black or African American |  |  |  |  | Infections and infestations | Bronchitis | Unexpected  Non-serious  Yes | Recovered/Resolved | 06Feb2016 | Not Related |
| 331-12-282 | 015-S7952 |  | UNITED STATES  Male  53Years  White |  |  |  |  | Infections and infestations | Infection | Unexpected  Serious  No | Not Recovered/Not Resolved | 24May2015 | Not Related |
| Psychiatric disorders | Middle insomnia | Unexpected  Non-serious  No | Not Recovered/Not Resolved | 26Apr2015 | Related |
| General disorders and administration site conditions | Systemic inflammatory response syndrome | Unexpected  Non-serious  Yes | Not Recovered/Not Resolved | 26May2015 | Not Related |
| 331-12-282 | 019-S8209 |  | UNITED STATES  Female  45Years  White | DUM PLC | PO  TABLET | 15Jul2015 | 15Jul2015 | Gastrointestinal disorders | Nausea | Unexpected  Non-serious  No | Recovered/Resolved | 21May2015 | Possibly Related |
| DUM PLC | PO  TABLET | 16Jul2015 | 22Jul2015 | Psychiatric disorders | Insomnia | Expected  Non-serious  No | Not Recovered/Not Resolved | 22May2015 | Possibly Related |
| DUM PLC | PO  TABLET | 23Jul2015 | 28Jul2015 | Metabolism and nutrition disorders | Decreased appetite | Unexpected  Non-serious  No | Recovered/Resolved | 23May2015 | Possibly Related |
| DUM PLC | PO  TABLET | 29Jul2015 | 02Aug2015 | Nervous system disorders | Somnolence | Expected  Non-serious  No | Recovered/Resolved | 26May2015 | Possibly Related |
| DUM PLC | PO  TABLET | 03Aug2015 | 04Aug2015 | Nervous system disorders | Somnolence | Expected  Non-serious  No | Recovered/Resolved | 28May2015 | Possibly Related |
| DUM PLC | PO  TABLET | 05Aug2015 | 11Aug2015 | Psychiatric disorders | Anorgasmia | Unexpected  Non-serious  No | Not Recovered/Not Resolved | 15Jun2015 | Possibly Related |
| Infections and infestations | Sinusitis | Unexpected  Non-serious  No | Recovered/Resolved | 23Jun2015 | Not Related |
| Infections and infestations | Bronchitis | Unexpected  Non-serious  No | Recovered/Resolved | 26Jun2015 | Not Related |
| Psychiatric disorders | Restlessness | Expected  Non-serious  Yes | Recovered/Resolved | 18Jul2015 | Possibly Related |
| Eye disorders | Blepharospasm | Unexpected  Non-serious  No | Recovered/Resolved | 18Jul2015 | Possibly Related |
| Nervous system disorders | Somnolence | Expected  Non-serious  No | Recovered/Resolved | 20Jul2015 | Possibly Related |
| Psychiatric disorders | Bruxism | Unexpected  Non-serious  No | Recovered/Resolved | 20Jul2015 | Possibly Related |
| Psychiatric disorders | Irritability | Unexpected  Non-serious  No | Not Recovered/Not Resolved | 20Jul2015 | Possibly Related |
| 331-12-282 | 322-S8267 |  | UNITED STATES  Male  37Years  White |  |  |  |  | Investigations | Blood creatine phosphokinase increased | Unexpected  Non-serious  No | Recovered/Resolved | 18Jun2015 | Not Related |
| Vascular disorders | Hypertension | Unexpected  Non-serious  Yes | Recovered/Resolved | 24Jun2015 | Not Related |
| 331-12-282 | 325-S8104 |  | UNITED STATES  Female  28Years  Black or African American |  |  |  |  | Gastrointestinal disorders | Constipation | Expected  Non-serious  No | Recovered/Resolved | 09May2015 | Possibly Related |
| Psychiatric disorders | Irritability | Unexpected  Non-serious  No | Not Recovered/Not Resolved | 19May2015 | Unlikely Related |
| General disorders and administration site conditions | Fatigue | Expected  Non-serious  Yes | Not Recovered/Not Resolved | 20May2015 | Related |
| Gastrointestinal disorders | Nausea | Unexpected  Non-serious  Yes | Not Recovered/Not Resolved | 20May2015 | Related |
| 331-12-282 | 325-S8225 |  | UNITED STATES  Female  61Years  White |  |  |  |  | Skin and subcutaneous tissue disorders | Rash | Unexpected  Non-serious  No | Recovered/Resolved | 04Jun2015 | Not Related |
| Psychiatric disorders | Somnambulism | Unexpected  Non-serious  No | Recovered/Resolved | 19Jun2015 | Not Related |
| Psychiatric disorders | Insomnia | Expected  Non-serious  Yes | Recovered/Resolved | 25Jun2015 | Possibly Related |
| Psychiatric disorders | Anxiety | Expected  Non-serious  No | Recovered/Resolved | 30Jun2015 | Possibly Related |
| Psychiatric disorders | Suicide attempt | Unexpected  Non-serious  Yes | Recovered/Resolved | 10Jul2015 | Possibly Related |
| Nervous system disorders | Restless legs syndrome | Unexpected  Non-serious  No | Recovered/Resolved | 14Jul2015 | Unlikely Related |
| Psychiatric disorders | Confusional state | Unexpected  Non-serious  No | Recovered/Resolved | 17Jul2015 | Not Related |
| 331-12-282 | 417-S8483 |  | RUSSIAN FEDERATION  Female  36Years  White | DUM BREX | PO  TABLET | 09Dec2015 | 15Dec2015 | Nervous system disorders | Headache | Unexpected  Non-serious  No | Recovered/Resolved | 16Oct2015 | Not Related |
| DUM BREX | PO  TABLET | 16Dec2015 | 22Dec2015 | Nervous system disorders | Somnolence | Expected  Non-serious  No | Recovered/Resolved | 11Dec2015 | Related |
| DUM BREX | PO  TABLET | 23Dec2015 | 25Dec2015 | Reproductive system and breast disorders | Breast engorgement | Unexpected  Non-serious  Yes | Recovered/Resolved | 12Dec2015 | Related |
| DUM BREX | PO  TABLET | 26Dec2015 | 29Dec2015 | Metabolism and nutrition disorders | Increased appetite | Expected  Non-serious  No | Recovered/Resolved | 12Dec2015 | Related |
| DUM BREX | PO  TABLET | 30Dec2015 | 05Jan2016 |
| 331-12-282 | 418-S8350 |  | RUSSIAN FEDERATION  Female  60Years  White | DUM PLC | PO  TABLET | 08Oct2015 | 14Oct2015 | Musculoskeletal and connective tissue disorders | Muscular weakness | Unexpected  Non-serious  No | Recovered/Resolved | 04Sep2015 | Possibly Related |
| DUM PLC | PO  TABLET | 15Oct2015 | 21Oct2015 | Ear and labyrinth disorders | Vertigo | Unexpected  Non-serious  No | Recovered/Resolved | 01Oct2015 | Possibly Related |
| DUM PLC | PO  TABLET | 22Oct2015 | 28Oct2015 | Cardiac disorders | Tachycardia | Unexpected  Non-serious  No | Recovered/Resolved | 19Oct2015 | Possibly Related |
| DUM PLC | PO  TABLET | 29Oct2015 | 05Nov2015 | Blood and lymphatic system disorders | White blood cell disorder | Unexpected  Non-serious  Yes | Recovered/Resolved | 06Nov2015 | Possibly Related |
| DUM PLC | PO  TABLET | 06Nov2015 | 12Nov2015 |
| DUM PLC | PO  TABLET | 13Nov2015 | 13Nov2015 |
| DUM PLC | PO  TABLET | 14Nov2015 | 15Nov2015 |
| 331-12-282 | 708-S8706 |  | UNITED STATES  Male  30Years  White |  |  |  |  | Cardiac disorders | Palpitations | Unexpected  Non-serious  Yes | Recovered/Resolved | 19Feb2016 | Possibly Related |
| Infections and infestations | Nasopharyngitis | Expected  Non-serious  No | Recovered/Resolved | 19Feb2016 | Not Related |
| 331-12-282 | 717-S8443 |  | UNITED STATES  Female  35Years  Other |  |  |  |  | Psychiatric disorders | Suicide attempt | Unexpected  Serious  No | Recovered/Resolved | 12Jan2016 | Not Related |
| Surgical and medical procedures | Hospitalisation | Unexpected  Serious  No | Recovered/Resolved | 12Jan2016 | Not Related |
| Gastrointestinal disorders | Nausea | Unexpected  Non-serious  No | Recovered/Resolved | 07Oct2015 | Possibly Related |
| Cardiac disorders | Palpitations | Unexpected  Non-serious  No | Recovered/Resolved | 14Oct2015 | Possibly Related |
| Psychiatric disorders | Insomnia | Expected  Non-serious  No | Not Recovered/Not Resolved | 14Oct2015 | Possibly Related |
| Psychiatric disorders | Anxiety | Expected  Non-serious  No | Not Recovered/Not Resolved | 14Oct2015 | Possibly Related |
| Psychiatric disorders | Restlessness | Expected  Non-serious  No | Recovered/Resolved | 03Nov2015 | Possibly Related |
| Nervous system disorders | Tremor | Expected  Non-serious  No | Recovered/Resolved | 03Nov2015 | Possibly Related |
| Skin and subcutaneous tissue disorders | Urticaria | Unexpected  Non-serious  Yes | Recovered/Resolved | 29Nov2015 | Possibly Related |
| Ear and labyrinth disorders | Vertigo | Unexpected  Non-serious  Yes | Recovered/Resolved | 29Nov2015 | Possibly Related |
| General disorders and administration site conditions | Crying | Unexpected  Non-serious  Yes | Recovered/Resolved | 29Nov2015 | Possibly Related |
| Skin and subcutaneous tissue disorders | Hyperhidrosis | Unexpected  Non-serious  Yes | Recovered/Resolved | 29Nov2015 | Possibly Related |
| Gastrointestinal disorders | Nausea | Unexpected  Non-serious  Yes | Recovered/Resolved | 29Nov2015 | Possibly Related |
| Infections and infestations | Vaginitis bacterial | Unexpected  Non-serious  No | Recovered/Resolved | 30Nov2015 | Not Related |
| 331-12-282 | 769-S8111 |  | POLAND  Female  32Years  White |  |  |  |  | Psychiatric disorders | Depressive symptom | Unexpected  Non-serious  Yes | Not Recovered/Not Resolved | 06May2015 | Possibly Related |
| 331-12-282 | 808-S8371 |  | UNITED STATES  Female  64Years  White |  |  |  |  | General disorders and administration site conditions | Facial pain | Unexpected  Serious  Yes | Recovered/Resolved | 21Sep2015 | Possibly Related |
| Musculoskeletal and connective tissue disorders | Neck pain | Unexpected  Serious  Yes | Recovered/Resolved | 21Sep2015 | Possibly Related |
| Injury, poisoning and procedural complications | Cervical vertebral fracture | Unexpected  Serious  Yes | Recovered/Resolved | 21Sep2015 | Possibly Related |
| Gastrointestinal disorders | Nausea | Unexpected  Non-serious  No | Recovered/Resolved | 16Sep2015 | Possibly Related |
| 331-12-282 | 808-S8678 |  | UNITED STATES  Female  20Years  White |  |  |  |  | Psychiatric disorders | Restlessness | Expected  Non-serious  Yes | Recovered/Resolved | 11Feb2016 | Possibly Related |
| 331-12-282 | 819-S8393 |  | UNITED STATES  Female  34Years  White |  |  |  |  | Skin and subcutaneous tissue disorders | Pruritus | Unexpected  Non-serious  No | Recovered/Resolved | 10Sep2015 | Unlikely Related |
| Infections and infestations | Nasopharyngitis | Expected  Non-serious  No | Recovered/Resolved | 18Sep2015 | Not Related |
| Nervous system disorders | Somnolence | Expected  Non-serious  Yes | Recovered/Resolved | 18Sep2015 | Related |
| Renal and urinary disorders | Pollakiuria | Unexpected  Non-serious  No | Recovered/Resolved | 20Sep2015 | Unlikely Related |
| General disorders and administration site conditions | Thirst | Unexpected  Non-serious  No | Recovered/Resolved | 20Sep2015 | Possibly Related |
| 331-12-282 | 820-S8148 |  | UNITED STATES  Female  42Years  White |  |  |  |  | Vascular disorders | Hypertension | Unexpected  Non-serious  Yes | Recovered/Resolved | 15May2015 | Possibly Related |
| 331-12-282 | 820-S8335 |  | UNITED STATES  Female  37Years  White |  |  |  |  | Vascular disorders | Deep vein thrombosis | Unexpected  Serious  Yes | Recovering/Resolving | 22Aug2015 | Unlikely Related |
| Vascular disorders | Aortic embolus | Unexpected  Serious  Yes | Recovering/Resolving | 22Aug2015 | Unlikely Related |
| 331-12-283 | 103-0177 |  | UNITED STATES  Male  78Years  White | DUMMY W | PO  TABLET | 21Apr2015 | 24Apr2015 | General disorders and administration site conditions | Pyrexia | Unexpected  Serious  No | Recovered/Resolved | 19Jun2015 | Not Related |
| DUMMY W | PO  TABLET | 25Apr2015 | 03May2015 | Respiratory, thoracic and mediastinal disorders | Pneumonia aspiration | Unexpected  Serious  Yes | Fatal | 22Jun2015 | Not Related |
| DUMMY W | PO  TABLET | 04May2015 | 05May2015 | Psychiatric disorders | Agitation | Expected  Non-serious  No | Recovered/Resolved | 12Jun2015 | Not Related |
| DUMMY W | PO  TABLET | 06May2015 | 07May2015 | Psychiatric disorders | Agitation | Expected  Non-serious  No | Recovered/Resolved | 16Jun2015 | Not Related |
| DUMMY W | PO  TABLET | 08May2015 | 09May2015 |
| DUMMY W | PO  TABLET | 10May2015 | 11May2015 |
| DUMMY W | PO  TABLET | 12May2015 | 13May2015 |
| DUMMY W | PO  TABLET | 14May2015 | 14May2015 |
| DUMMY W | PO  TABLET | 15May2015 | 19May2015 |
| DUMMY W | PO  TABLET | 20May2015 | 26May2015 |
| DUMMY W | PO  TABLET | 27May2015 | 28May2015 |
| DUMMY W | PO  TABLET | 29May2015 | 29May2015 |
| DUMMY W | PO  TABLET | 30May2015 | 02Jun2015 |
| DUMMY W | PO  TABLET | 03Jun2015 | 11Jun2015 |
| DUMMY W | PO  TABLET | 12Jun2015 | 13Jun2015 |
| DUMMY W | PO  TABLET | 14Jun2015 | 16Jun2015 |
| DUMMY W | PO  TABLET | 17Jun2015 | 17Jun2015 |
| DUMMY W | PO  TABLET | 18Jun2015 | 22Jun2015 |
| DUMMY W | PO  TABLET | 23Jun2015 | 23Jun2015 |
| DUMMY W | PO  TABLET | 24Jun2015 | 24Jun2015 |
| DUMMY W | PO  TABLET | 25Jun2015 | 07Jul2015 |
| 331-12-283 | 111-0290 |  | UNITED STATES  Male  85Years  White | DUMMY W | PO  TABLET | 25Aug2015 | 26Aug2015 | Infections and infestations | Cellulitis | Unexpected  Serious  No | Recovered/Resolved | 12Aug2015 | Not Related |
| DUMMY W | PO  TABLET | 27Aug2015 | 31Aug2015 | Infections and infestations | Clostridium difficile colitis | Unexpected  Serious  No | Recovered/Resolved | 25Sep2015 | Unlikely Related |
| DUMMY W | PO  TABLET | 01Sep2015 | 09Sep2015 | Infections and infestations | Clostridium difficile colitis | Unexpected  Serious  Yes | Recovered/Resolved | 23Oct2015 | Not Related |
| DUMMY W | PO  TABLET | 10Sep2015 | 17Sep2015 |
| DUMMY W | PO  TABLET | 18Sep2015 | 21Sep2015 |
| DUMMY W | PO  TABLET | 22Sep2015 | 23Sep2015 |
| DUMMY W | PO  TABLET | 24Sep2015 | 01Oct2015 |
| DUMMY W | PO  TABLET | 02Oct2015 | 05Oct2015 |
| DUMMY W | PO  TABLET | 06Oct2015 | 06Oct2015 |
| DUMMY W | PO  TABLET | 07Oct2015 | 23Oct2015 |
| DUMMY W | PO  TABLET | 16Oct2015 | 20Oct2015 |
| DUMMY W | PO  TABLET | 21Oct2015 | 22Oct2015 |
| DUMMY W | PO  TABLET | 23Oct2015 | 01Nov2015 |
| DUMMY W | PO  TABLET | 02Nov2015 | 04Nov2015 |
| DUMMY W | PO  TABLET | 05Nov2015 | 10Nov2015 |
| DUMMY W | PO  TABLET | 11Nov2015 | 17Nov2015 |
| DUMMY W | PO  TABLET | 18Nov2015 | 19Nov2015 |
| 331-12-283 | 118-0176 |  | UNITED STATES  Female  80Years  Black or African American | DUMMY W | PO  TABLET | 25Jun2015 | 29Jun2015 | Psychiatric disorders | Agitation | Expected  Serious  No | Recovered/Resolved | 27May2015 | Not Related |
| DUMMY W | PO  TABLET | 30Jun2015 | 06Jul2015 | Blood and lymphatic system disorders | Anaemia | Unexpected  Serious  Yes | Recovered/Resolved | 11Sep2015 | Not Related |
| DUMMY W | PO  TABLET | 07Jul2015 | 08Jul2015 |
| DUMMY W | PO  TABLET | 09Jul2015 | 15Jul2015 |
| DUMMY W | PO  TABLET | 16Jul2015 | 21Jul2015 |
| DUMMY W | PO  TABLET | 22Jul2015 | 28Jul2015 |
| DUMMY W | PO  TABLET | 29Jul2015 | 03Aug2015 |
| DUMMY W | PO  TABLET | 04Aug2015 | 10Aug2015 |
| DUMMY W | PO  TABLET | 11Aug2015 | 19Aug2015 |
| DUMMY W | PO  TABLET | 20Aug2015 | 26Aug2015 |
| DUMMY W | PO  TABLET | 27Aug2015 | 02Sep2015 |
| DUMMY W | PO  TABLET | 03Sep2015 | 11Sep2015 |
| DUMMY W | PO  TABLET | 12Sep2015 | 16Sep2015 |
| DUMMY W | PO  TABLET | 17Sep2015 | 18Sep2015 |
| 331-12-283 | 121-0207 |  | UNITED STATES  Female  84Years  White | DUMMY Y | PO  TABLET | 02Jun2015 | 04Jun2015 | Injury, poisoning and procedural complications | Patella fracture | Unexpected  Serious  Yes | Not Recovered/Not Resolved | 01Jul2015 | Not Related |
| DUMMY Y | PO  TABLET | 05Jun2015 | 11Jun2015 | Metabolism and nutrition disorders | Hyponatraemia | Unexpected  Non-serious  No | Recovered/Resolved | 29Apr2015 | Not Related |
| DUMMY Y | PO  TABLET | 12Jun2015 | 15Jun2015 | Injury, poisoning and procedural complications | Fall | Unexpected  Non-serious  No | Recovered/Resolved | 30Jun2015 | Not Related |
| DUMMY Y | PO  TABLET | 16Jun2015 | 22Jun2015 |
| DUMMY Y | PO  TABLET | 23Jun2015 | 29Jun2015 |
| DUMMY Y | PO  TABLET | 30Jun2015 | 01Jul2015 |
| DUMMY Y | PO  TABLET | 02Jul2015 | 06Jul2015 |
| 331-12-283 | 121-0208 |  | UNITED STATES  Male  76Years  White | DUMMY W | PO  TABLET | 18Nov2015 | 20Nov2015 | Gastrointestinal disorders | Pancreatitis | Unexpected  Serious  Yes | Recovered/Resolved | 30Nov2015 | Not Related |
| DUMMY W | PO  TABLET | 21Nov2015 | 27Nov2015 | Investigations | White blood cell count decreased | Unexpected  Non-serious  No | Recovered/Resolved | 15Dec2015 | Not Related |
| DUMMY W | PO  TABLET | 28Nov2015 | 30Nov2015 |
| DUMMY W | PO  TABLET | 01Dec2015 | 02Dec2015 |
| DUMMY W | PO  TABLET | 03Dec2015 | 04Dec2015 |
| DUMMY W | PO  TABLET | 05Dec2015 | 11Dec2015 |
| DUMMY W | PO  TABLET | 12Dec2015 | 15Dec2015 |
| DUMMY W | PO  TABLET | 16Dec2015 | 22Dec2015 |
| DUMMY W | PO  TABLET | 23Dec2015 | 29Dec2015 |
| DUMMY W | PO  TABLET | 30Dec2015 | 05Jan2016 |
| DUMMY W | PO  TABLET | 06Jan2016 | 12Jan2016 |
| DUMMY W | PO  TABLET | 13Jan2016 | 19Jan2016 |
| DUMMY W | PO  TABLET | 20Jan2016 | 26Jan2016 |
| DUMMY W | PO  TABLET | 27Jan2016 | 02Feb2016 |
| DUMMY W | PO  TABLET | 03Feb2016 | 09Feb2016 |
| 331-12-283 | 134-0314 |  | UNITED STATES  Female  72Years  White | DUMMY W | PO  TABLET | 26Sep2015 | 28Sep2015 | Gastrointestinal disorders | Constipation | Expected  Non-serious  No | Recovered/Resolved | 20Oct2015 | Possibly Related |
| DUMMY W | PO  TABLET | 29Sep2015 | 05Oct2015 | Gastrointestinal disorders | Constipation | Expected  Non-serious  No | Recovered/Resolved | 30Oct2015 | Possibly Related |
| DUMMY W | PO  TABLET | 06Oct2015 | 09Oct2015 | Metabolism and nutrition disorders | Feeding disorder | Unexpected  Non-serious  Yes | Recovered/Resolved | 04Nov2015 | Possibly Related |
| DUMMY W | PO  TABLET | 10Oct2015 | 16Oct2015 | Vascular disorders | Orthostatic hypotension | Unexpected  Non-serious  No | Recovered/Resolved | 20Nov2015 | Possibly Related |
| DUMMY W | PO  TABLET | 17Oct2015 | 23Oct2015 |
| DUMMY W | PO  TABLET | 24Oct2015 | 30Oct2015 |
| DUMMY W | PO  TABLET | 31Oct2015 | 06Nov2015 |
| DUMMY W | PO  TABLET | 07Nov2015 | 13Nov2015 |
| DUMMY W | PO  TABLET | 14Nov2015 | 20Nov2015 |
| DUMMY W | PO  TABLET | 21Nov2015 | 27Nov2015 |
| DUMMY W | PO  TABLET | 28Nov2015 | 04Dec2015 |
| 331-12-283 | 141-0405 |  | CROATIA (local name: Hrvatska)  Female  77Years  White | DUMMY Y | PO  TABLET | 19Jan2016 | 21Jan2016 | Nervous system disorders | Tremor | Expected  Non-serious  No | Recovered/Resolved | 02Feb2016 | Possibly Related |
| DUMMY Y | 0mg(DAY)  PO  TABLET | 22Jan2016 | 01Feb2016 | Gastrointestinal disorders | Constipation | Expected  Non-serious  No | Recovered/Resolved | 13Feb2016 | Possibly Related |
| DUMMY Y | 0mg(DAY)  PO  TABLET | 02Feb2016 | 15Feb2016 | Nervous system disorders | Tremor | Expected  Non-serious  Yes | Recovered/Resolved | 03Mar2016 | Possibly Related |
| DUMMY Y | 0mg(DAY)  PO  TABLET | 16Feb2016 | 29Feb2016 | Nervous system disorders | Hypokinesia | Unexpected  Non-serious  Yes | Recovered/Resolved | 03Mar2016 | Possibly Related |
| DUMMY Y | PO  TABLET | 01Mar2016 | 06Mar2016 | Nervous system disorders | Dysarthria | Unexpected  Non-serious  Yes | Recovered/Resolved | 03Mar2016 | Possibly Related |
| Psychiatric disorders | Disorientation | Unexpected  Non-serious  Yes | Recovered/Resolved | 03Mar2016 | Possibly Related |
| 331-12-283 | 143-0132 |  | CROATIA (local name: Hrvatska)  Female  74Years  White | DUMMY X | PO  TABLET | 27Oct2015 | 29Oct2015 | Gastrointestinal disorders | Dyspepsia | Expected  Non-serious  No | Recovered/Resolved | 27Oct2015 | Possibly Related |
| DUMMY X | PO  TABLET | 30Oct2015 | 07Nov2015 | Psychiatric disorders | Insomnia | Expected  Non-serious  No | Not Recovered/Not Resolved | Dec2015 | Possibly Related |
| DUMMY X | PO  TABLET | 08Nov2015 | 09Nov2015 | General disorders and administration site conditions | Gait disturbance | Unexpected  Non-serious  No | Recovered/Resolved | 01Dec2015 | Possibly Related |
| DUMMY X | PO  TABLET | 10Nov2015 | 16Nov2015 | Nervous system disorders | Parkinsonism | Unexpected  Non-serious  Yes | Recovered/Resolved | 15Dec2015 | Possibly Related |
| DUMMY X | PO  TABLET | 17Nov2015 | 22Nov2015 | Psychiatric disorders | Agitation | Expected  Non-serious  No | Not Recovered/Not Resolved | 16Jan2016 | Possibly Related |
| DUMMY X | PO  TABLET | 23Nov2015 | 23Nov2015 |
| DUMMY X | PO  TABLET | 24Nov2015 | 30Nov2015 |
| DUMMY X | PO  TABLET | 01Dec2015 | 07Dec2015 |
| DUMMY X | PO  TABLET | 08Dec2015 | 14Dec2015 |
| DUMMY X | PO  TABLET | 15Dec2015 | 17Dec2015 |
| DUMMY X | PO  TABLET | 18Dec2015 | 23Dec2015 |
| 331-12-283 | 144-0201 |  | CROATIA (local name: Hrvatska)  Female  67Years  White | DUMMY Z | PO  TABLET | 15May2015 | 17May2015 | Psychiatric disorders | Intentional self-injury | Unexpected  Serious  Yes | Recovered/Resolved | 18May2015 | Not Related |
| DUMMY Z | PO  TABLET | 18May2015 | 18May2015 |
| DUMMY Z | PO  TABLET | 19May2015 | 27May2015 |
| 331-12-283 | 145-0350 |  | CROATIA (local name: Hrvatska)  Male  78Years  White | DUMMY Y | PO  TABLET | 10Nov2015 | 12Nov2015 | Nervous system disorders | Psychomotor hyperactivity | Unexpected  Serious  Yes | Recovered/Resolved | 02Jan2016 | Not Related |
| DUMMY Y | PO  TABLET | 13Nov2015 | 17Nov2015 |
| DUMMY Y | PO  TABLET | 18Nov2015 | 24Nov2015 |
| DUMMY Y | PO  TABLET | 25Nov2015 | 01Dec2015 |
| DUMMY Y | PO  TABLET | 02Dec2015 | 09Dec2015 |
| DUMMY Y | PO  TABLET | 10Dec2015 | 16Dec2015 |
| DUMMY Y | PO  TABLET | 17Dec2015 | 22Dec2015 |
| DUMMY Y | PO  TABLET | 23Dec2015 | 29Dec2015 |
| DUMMY Y | PO  TABLET | 30Dec2015 | 01Jan2016 |
| 331-12-283 | 149-0297 |  | CROATIA (local name: Hrvatska)  Male  67Years  White | DUMMY Z | PO  TABLET | 09Sep2015 | 11Sep2015 | Nervous system disorders | Epilepsy | Unexpected  Serious  Yes | Recovered/Resolved | 02Nov2015 | Unlikely Related |
| DUMMY Z | PO  TABLET | 12Sep2015 | 19Sep2015 |
| DUMMY Z | PO  TABLET | 20Sep2015 | 22Sep2015 |
| DUMMY Z | PO  TABLET | 23Sep2015 | 01Oct2015 |
| DUMMY Z | PO  TABLET | 02Oct2015 | 06Oct2015 |
| DUMMY Z | PO  TABLET | 07Oct2015 | 09Oct2015 |
| DUMMY Z | PO  TABLET | 10Oct2015 | 20Oct2015 |
| DUMMY Z | PO  TABLET | 21Oct2015 | 27Oct2015 |
| DUMMY Z | PO  TABLET | 28Oct2015 | 18Nov2015 |
| 331-12-283 | 152-0414 |  | GERMANY  Male  76Years  White | DUMMY Y | PO  TABLET | 19Feb2016 | 22Feb2016 | Psychiatric disorders | Delusion | Unexpected  Serious  Yes | Not Recovered/Not Resolved | 07Apr2016 | Not Related |
| DUMMY Y | PO  TABLET | 23Feb2016 | 29Feb2016 | General disorders and administration site conditions | Fatigue | Expected  Non-serious  No | Not Recovered/Not Resolved | 01Mar2016 | Possibly Related |
| DUMMY Y | PO  TABLET | 01Mar2016 | 03Mar2016 | Metabolism and nutrition disorders | Increased appetite | Expected  Non-serious  No | Not Recovered/Not Resolved | 01Mar2016 | Possibly Related |
| DUMMY Y | PO  TABLET | 04Mar2016 | 10Mar2016 |
| DUMMY Y | PO  TABLET | 11Mar2016 | 17Mar2016 |
| DUMMY Y | PO  TABLET | 18Mar2016 | 24Mar2016 |
| DUMMY Y | PO  TABLET | 25Mar2016 | 31Mar2016 |
| 331-12-283 | 159-0188 |  | GERMANY  Male  77Years  White | DUMMY Z | PO  TABLET | 26Nov2015 | 30Nov2015 | Nervous system disorders | Balance disorder | Unexpected  Non-serious  Yes | Recovered/Resolved | 06Jan2016 | Unlikely Related |
| DUMMY Z | PO  TABLET | 01Dec2015 | 09Dec2015 |
| DUMMY Z | PO  TABLET | 10Dec2015 | 18Dec2015 |
| DUMMY Z | PO  TABLET | 19Dec2015 | 21Dec2015 |
| DUMMY Z | PO  TABLET | 22Dec2015 | 30Dec2015 |
| DUMMY Z | PO  TABLET | 31Dec2015 | 05Jan2016 |
| DUMMY Z | PO  TABLET | 06Jan2016 | 10Jan2016 |
| DUMMY Z | PO  TABLET | 11Jan2016 | 21Jan2016 |
| 331-12-283 | 171-0369 |  | RUSSIAN FEDERATION  Female  60Years  White | DUMMY Z | PO  TABLET | 27Nov2015 | 30Nov2015 | Nervous system disorders | Dementia | Unexpected  Serious  Yes | Not Recovered/Not Resolved | 27Jan2016 | Possibly Related |
| DUMMY Z | PO  TABLET | 01Dec2015 | 07Dec2015 | Psychiatric disorders | Abnormal behaviour | Unexpected  Serious  Yes | Not Recovered/Not Resolved | 27Jan2016 | Possibly Related |
| DUMMY Z | PO  TABLET | 08Dec2015 | 14Dec2015 |
| DUMMY Z | PO  TABLET | 15Dec2015 | 23Dec2015 |
| DUMMY Z | PO  TABLET | 24Dec2015 | 30Dec2015 |
| DUMMY Z | PO  TABLET | 31Dec2015 | 04Jan2016 |
| DUMMY Z | PO  TABLET | 05Jan2016 | 11Jan2016 |
| DUMMY Z | PO  TABLET | 12Jan2016 | 19Jan2016 |
| DUMMY Z | PO  TABLET | 20Jan2016 | 26Jan2016 |
| DUMMY Z | PO  TABLET | 27Jan2016 | 29Jan2016 |
| 331-12-283 | 172-0318 |  | RUSSIAN FEDERATION  Female  77Years  White | DUMMY Z | PO  TABLET | 02Oct2015 | 04Oct2015 | Blood and lymphatic system disorders | Anaemia | Unexpected  Non-serious  No | Recovered/Resolved | 01Oct2015 | Not Related |
| DUMMY Z | PO  TABLET | 05Oct2015 | 11Oct2015 | Infections and infestations | Respiratory tract infection | Unexpected  Non-serious  No | Recovered/Resolved | 19Nov2015 | Not Related |
| DUMMY Z | PO  TABLET | 12Oct2015 | 15Oct2015 | Psychiatric disorders | Agitation | Expected  Non-serious  Yes | Recovered/Resolved | 29Nov2015 | Not Related |
| DUMMY Z | PO  TABLET | 16Oct2015 | 22Oct2015 | Psychiatric disorders | Insomnia | Expected  Non-serious  No | Recovered/Resolved | 29Nov2015 | Not Related |
| DUMMY Z | PO  TABLET | 23Oct2015 | 29Oct2015 |
| DUMMY Z | PO  TABLET | 30Oct2015 | 06Nov2015 |
| DUMMY Z | PO  TABLET | 07Nov2015 | 12Nov2015 |
| DUMMY Z | PO  TABLET | 13Nov2015 | 19Nov2015 |
| DUMMY Z | PO  TABLET | 20Nov2015 | 26Nov2015 |
| DUMMY Z | PO  TABLET | 27Nov2015 | 30Nov2015 |
| 331-12-283 | 176-0181 |  | SERBIA  Female  73Years  White | DUMMY X | PO  TABLET | 28Apr2015 | 30Apr2015 | Gastrointestinal disorders | Diarrhoea | Unexpected  Non-serious  No | Recovered/Resolved | 25May2015 | Not Related |
| DUMMY X | PO  TABLET | 01May2015 | 07May2015 | Metabolism and nutrition disorders | Electrolyte imbalance | Unexpected  Non-serious  Yes | Recovered/Resolved | 22Jun2015 | Not Related |
| DUMMY X | PO  TABLET | 08May2015 | 11May2015 | Investigations | Haemoglobin decreased | Unexpected  Non-serious  No | Recovering/Resolving | 29Jun2015 | Not Related |
| DUMMY X | PO  TABLET | 12May2015 | 18May2015 | Investigations | Glomerular filtration rate increased | Unexpected  Non-serious  No | Recovering/Resolving | 29Jun2015 | Not Related |
| DUMMY X | PO  TABLET | 19May2015 | 25May2015 |
| DUMMY X | PO  TABLET | 26May2015 | 01Jun2015 |
| DUMMY X | PO  TABLET | 02Jun2015 | 08Jun2015 |
| DUMMY X | PO  TABLET | 09Jun2015 | 15Jun2015 |
| DUMMY X | PO  TABLET | 16Jun2015 | 22Jun2015 |
| DUMMY X | PO  TABLET | 23Jun2015 | 28Jun2015 |
| DUMMY X | PO  TABLET | 29Jun2015 | 29Jun2015 |
| 331-12-284 | 528-1161 |  | Female  77Years  White | DUMMY Y | PO  TABLET | 05Nov2015 | 08Nov2015 | Nervous system disorders | Seizure | Unexpected  Serious  Yes | Recovered/Resolved | 10Jan2016 | Possibly Related |
| DUMMY Y |  | 05Nov2015 | 10Jan2016 | Psychiatric disorders | Insomnia | Expected  Non-serious  No | Recovering/Resolving | 26Nov2015 | Possibly Related |
| DUMMY Y | PO  TABLET | 09Nov2015 | 15Nov2015 | Gastrointestinal disorders | Faecal incontinence | Unexpected  Non-serious  No | Recovered/Resolved | 29Nov2015 | Unlikely Related |
| DUMMY Y | PO  TABLET | 16Nov2015 | 17Nov2015 | Renal and urinary disorders | Urinary incontinence | Unexpected  Non-serious  No | Recovered/Resolved | 29Nov2015 | Unlikely Related |
| DUMMY Y | PO  TABLET | 18Nov2015 | 24Nov2015 | Gastrointestinal disorders | Faecal incontinence | Unexpected  Non-serious  No | Recovered/Resolved | 24Dec2015 | Unlikely Related |
| DUMMY Y | PO  TABLET | 25Nov2015 | 03Dec2015 | Gastrointestinal disorders | Faecal incontinence | Unexpected  Non-serious  No | Recovered/Resolved | 28Dec2015 | Unlikely Related |
| DUMMY Y | PO  TABLET | 04Dec2015 | 10Dec2015 |
| DUMMY Y | PO  TABLET | 11Dec2015 | 16Dec2015 |
| DUMMY Y | PO  TABLET | 17Dec2015 | 23Dec2015 |
| DUMMY Y | PO  TABLET | 24Dec2015 | 30Dec2015 |
| DUMMY Y |  | 29Dec2015 | 10Jan2016 |
| DUMMY Y |  | 30Dec2015 | 10Jan2016 |
| DUMMY Y | PO  TABLET | 31Dec2015 | 06Jan2016 |
| DUMMY Y | PO  TABLET | 07Jan2016 | 09Jan2016 |
| DUMMY Y |  | 08Jan2016 | 10Jan2016 |
| DUMMY Y |  | 09Jan2016 | 10Jan2016 |
| 331-12-284 | 588-1141 |  | UKRAINE  Male  58Years  White | DUMMY X | PO  TABLET | 25Jun2015 | 27Jun2015 | Nervous system disorders | Seizure | Unexpected  Non-serious  Yes | Recovered/Resolved | 30Jun2015 | Possibly Related |
| DUMMY X |  | 25Jun2015 | 30Jun2015 | Psychiatric disorders | Agitation | Expected  Non-serious  No | Recovered/Resolved | 04Jul2015 | Not Related |
| DUMMY X | PO  TABLET | 28Jun2015 | 29Jun2015 |
| DUMMY X |  | 28Jun2015 | 30Jun2015 |
| DUMMY X |  | 29Jun2015 | 30Jun2015 |
| DUMMY X | PO  TABLET | 30Jun2015 | 30Jun2015 |
| 331-12-284 | 589-1145 |  | UKRAINE  Male  61Years  White | DUMMY Y | PO  TABLET | 01Jul2015 | 03Jul2015 | Nervous system disorders | Seizure | Unexpected  Serious  Yes | Recovered/Resolved | 18Aug2015 | Possibly Related |
| DUMMY Y |  | 01Jul2015 | 18Aug2015 | Vascular disorders | Hypertensive crisis | Unexpected  Serious  Yes | Recovered/Resolved | 18Aug2015 | Possibly Related |
| DUMMY Y | PO  TABLET | 04Jul2015 | 10Jul2015 | Investigations | Weight increased | Expected  Non-serious  No | Not Recovered/Not Resolved | 25Aug2015 | Unlikely Related |
| DUMMY Y | PO  TABLET | 11Jul2015 | 14Jul2015 | Gastrointestinal disorders | Vomiting | Unexpected  Non-serious  No | Recovered/Resolved | 26Aug2015 | Not Related |
| DUMMY Y | PO  TABLET | 15Jul2015 | 21Jul2015 |
| DUMMY Y | PO  TABLET | 22Jul2015 | 28Jul2015 |
| DUMMY Y | PO  TABLET | 29Jul2015 | 04Aug2015 |
| DUMMY Y | PO  TABLET | 05Aug2015 | 11Aug2015 |
| DUMMY Y | PO  TABLET | 12Aug2015 | 17Aug2015 |
| DUMMY Y |  | 16Aug2015 | 18Aug2015 |
| DUMMY Y |  | 17Aug2015 | 18Aug2015 |
| DUMMY Y | PO  TABLET | 18Aug2015 | 25Aug2015 |
| 331-12-284 | 602-1109 |  | SLOVENIA  Female  87Years  White | DUMMY X | PO  TABLET | 24Apr2015 | 26Apr2015 | Injury, poisoning and procedural complications | Femur fracture | Unexpected  Serious  Yes | Recovered/Resolved with Sequelae | 13Jun2015 | Not Related |
| DUMMY X |  | 24Apr2015 | 13Jun2015 | Injury, poisoning and procedural complications | Pubis fracture | Unexpected  Non-serious  No | Recovering/Resolving | 21Apr2015 | Not Related |
| DUMMY X | PO  TABLET | 27Apr2015 | 03May2015 | Gastrointestinal disorders | Nausea | Unexpected  Non-serious  No | Recovered/Resolved | 02May2015 | Not Related |
| DUMMY X | PO  TABLET | 04May2015 | 10May2015 | Gastrointestinal disorders | Nausea | Unexpected  Non-serious  No | Recovered/Resolved | 12May2015 | Not Related |
| DUMMY X | PO  TABLET | 11May2015 | 17May2015 | Gastrointestinal disorders | Nausea | Unexpected  Non-serious  No | Recovered/Resolved | 14May2015 | Not Related |
| DUMMY X | PO  TABLET | 18May2015 | 24May2015 | Gastrointestinal disorders | Periodontal disease | Unexpected  Non-serious  No | Recovered/Resolved | 18May2015 | Not Related |
| DUMMY X | PO  TABLET | 25May2015 | 31May2015 | Gastrointestinal disorders | Nausea | Unexpected  Non-serious  No | Recovered/Resolved | 01Jun2015 | Not Related |
| DUMMY X | PO  TABLET | 01Jun2015 | 07Jun2015 | Infections and infestations | Urinary tract infection | Unexpected  Non-serious  No | Recovered/Resolved | 01Jul2015 | Not Related |
| DUMMY X | PO  TABLET | 08Jun2015 | 12Jun2015 |
| DUMMY X | PO  TABLET | 13Jun2015 | 14Jun2015 |
| DUMMY X | PO  TABLET | 15Jun2015 | 15Jun2015 |
| DUMMY X | PO  TABLET | 16Jun2015 | 17Jun2015 |
| DUMMY X | PO  TABLET | 18Jun2015 | 18Jun2015 |
| DUMMY X | PO  TABLET | 19Jun2015 | 27Jun2015 |
| DUMMY X | PO  TABLET | 28Jun2015 | 03Jul2015 |
| DUMMY X | PO  TABLET | 04Jul2015 | 10Jul2015 |
| DUMMY X | PO  TABLET | 11Jul2015 | 16Jul2015 |
| DUMMY X |  | 15Jul2015 | 13Jun2015 |
| DUMMY X |  | 16Jul2015 | 13Jun2015 |
| 331-13-214 | 014-S3043 |  | UNITED STATES  Male  44Years  White | DUM PLC | PO  TABLET | 28May2015 | 04Jun2015 | Psychiatric disorders | Restlessness | Expected  Non-serious  No | Recovered/Resolved | 11Jun2015 | Possibly Related |
| DUM PLC | PO  TABLET | 05Jun2015 | 10Jun2015 | Psychiatric disorders | Anxiety | Expected  Non-serious  No | Recovered/Resolved | 11Jun2015 | Possibly Related |
| DUM PLC | PO  TABLET | 11Jun2015 | 18Jun2015 | Psychiatric disorders | Insomnia | Expected  Non-serious  Yes | Recovered/Resolved | 18Jun2015 | Related |
| DUM PLC | PO  TABLET | 19Jun2015 | 24Jun2015 | Investigations | Blood pressure increased | Unexpected  Non-serious  No | Recovered/Resolved | 24Jun2015 | Possibly Related |
| 331-13-214 | 320-S3637 |  | UNITED STATES  Female  39Years  Black or African American | DUM PLC | PO  TABLET | 25Feb2016 | 29Feb2016 | Skin and subcutaneous tissue disorders | Dermatitis atopic | Unexpected  Non-serious  Yes | Recovered/Resolved | 08Jan2016 | Not Related |
| DUM PLC | PO  TABLET | 01Mar2016 | 03Mar2016 | Nervous system disorders | Hypersomnia | Unexpected  Non-serious  No | Recovered/Resolved | 15Jan2016 | Possibly Related |
| Metabolism and nutrition disorders | Increased appetite | Expected  Non-serious  No | Recovered/Resolved | 15Jan2016 | Possibly Related |
| Respiratory, thoracic and mediastinal disorders | Cough | Unexpected  Non-serious  Yes | Recovered/Resolved | 10Feb2016 | Not Related |
| 331-13-214 | 392-S2972 |  | GERMANY  Male  52Years  White | DUM 2MG | PO  TABLET | 07May2015 | 12May2015 | Investigations | White blood cell count increased | Unexpected  Non-serious  No | Recovered/Resolved | 07May2015 | Possibly Related |
| DUM 2MG | PO  TABLET | 13May2015 | 20May2015 | Investigations | Gamma-glutamyltransferase increased | Unexpected  Non-serious  No | Not Recovered/Not Resolved | 07May2015 | Possibly Related |
| DUM 2MG | PO  TABLET | 21May2015 | 27May2015 | Gastrointestinal disorders | Vomiting | Unexpected  Non-serious  Yes | Recovered/Resolved | 28May2015 | Possibly Related |
| DUM 2MG | PO  TABLET | 28May2015 | 29May2015 | Gastrointestinal disorders | Diarrhoea | Unexpected  Non-serious  Yes | Recovered/Resolved | 28May2015 | Possibly Related |
| DUM 2MG | PO  TABLET | 30May2015 | 31May2015 |
| DUM 2MG | PO  TABLET | 01Jun2015 | 03Jun2015 |
| DUM 2MG | PO  TABLET | 04Jun2015 | 10Jun2015 |
| DUM 2MG | PO  TABLET | 11Jun2015 | 17Jun2015 |
| 331-13-214 | 704-S2834 |  | UNITED STATES  Male  39Years  Other | DUM PLC | PO  TABLET | 31Mar2015 | 06Apr2015 | Psychiatric disorders | Anxiety | Expected  Non-serious  Yes | Not Recovered/Not Resolved | 01May2015 | Not Related |
| DUM PLC | PO  TABLET | 07Apr2015 | 13Apr2015 |
| DUM PLC | PO  TABLET | 14Apr2015 | 20Apr2015 |
| DUM PLC | PO  TABLET | 21Apr2015 | 27Apr2015 |
| DUM PLC | PO  TABLET | 28Apr2015 | 02May2015 |
| DUM PLC | PO  TABLET | 03May2015 | 04May2015 |