Table G-3. Final health outcomes in controlled studies comparing innovator versus generic antiepileptic drugs

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Study, Year | Group | N | Deaths | Office/ER Visits (n) | Hospitalizations, Events (n) | Hospital Duration, Mean (SD) | Composite of Ambulance/ER/ Hospitalizations, Events (n) | Loss of Drivers License, Events (n) | Loss of Employment, Events (n) |
| Unspecified Innovator and Brand Antiepileptic Drug Products |
| Rascati, 2009 | Cases | 991 | - | - | - | - | - | - | - |
| Controls | 2973 | - | - | - | - | - | - | - |
| Zachry, 2009 | Cases | 416 | - | - | - | - | - | - | - |
| Controls | 1248 | - | - | - | - | - | - | - |
| Devine, 2010 | Cases | 2949 | - |  |  | - | - | - | - |
| Controls | 8847 | - |  |  | - | - | - | - |
| Labiner, 2010a | Branded carbamazepine, gabapentin, phenytoin, primidone, zonisamide (manufacturer not reported) | 18,125 | - | 11.86 events/person-years | 0.15 events/person-years | 1.02 days/event | - | - | - |
| Carbamazepine, gabapentin, phenytoin, primidone, zonisamide (manufacturer not reported) |  | - | 14.26 events/person-years (unadjusted rate ratio with 95% CI = 1.20 (1.19-1.21); adjusted rate ratio (1.20 (1.19-1.21)) | 0.20 events/person-years(unadjusted rate ratio with 95% CI = 1.35 (1.27-1.43); adjusted rate ratio (1.31 (1.24-1.40)) | 1.38 days/events(unadjusted rate ratio with 95% CI = 1.36 (1.33-1.39); adjusted rate ratio (1.33 (1.30-1.36)) | - | - | - |

| Table G-3. Final health outcomes in controlled studies comparing innovator versus generic antiepileptic drugs (continued) |
| --- |
| Study, Year | Group | N | Deaths | Office/ER Visits (n) | Hospitalizations, Events (n) | Hospital Duration, Mean (SD) | Composite of Ambulance/ER/ Hospitalizations, Events (n) | Loss of Drivers License, Events (n) | Loss of Employment, Events (n) |
| Labiner, 2010b | Branded carbamazepine, gabapentin, phenytoin, primidone, zonisamide (manufacturer not reported) | 15,500 | - | 23.33 events/person-years | 0.34 events/person-years | 2.33 days/event | - | - | - |
| Carbamazepine, gabapentin, phenytoin, primidone, zonisamide (manufacturer not reported) |  | - | 28.36 events/person-years (unadjusted rate ratio with 95% CI = 1.22 (1.21-1.22); adjusted rate ratio (1.16 (1.16-1.17)) | 0.47 events/person-years(unadjusted rate ratio with 95% CI = 1.38 (1.32-1.43); adjusted rate ratio (1.30 (1.25-1.36)) | 3.29 days/event(unadjusted rate ratio with 95% CI = 1.41 (1.39-1.43); adjusted rate ratio (1.34 (1.32-1.36)) | - | - | - |
| Carbamazepine |
| Kauko, 1974a | Tegretol (Ciba-Geigy) Tablets | 10 | - | - | - | - | - | - | - |
| Generic Carbamazepine (Laake Oy) Tablets |  | - | - | - | - | - | - | - |
| Kauko, 1974b | Tegretol (Ciba-Geigy) Tablets | 10 | - | - | - | - | - | - | - |
| Generic Carbamazepine (Laake Oy) Tablets |  | - | - | - | - | - | - | - |
| Glende, 1983 | Tegretol (Ciba-Geigy) Tablets | 5 | 0 | - | - | - | - | - | - |
| Carbamazepine (AWD Dresden) Tablets |  | 0 | - | - | - | - | - | - |
| Jumao-as, 1989 | Tegretol (Ciba-Geigy) Tablets | 10 | 0 | - | - | - | - | - | - |
| Generic Carbamazepine (Parke Davis) Tablets |  | 0 | - | - | - | - | - | - |
| Hartley, 1990 | Tegretol (Ciba-Geigy) | 23 | 0 | - | - | - | - | - | - |
| Carbamazepine (Ethical Generics) |  | 0 | - | - | - | - | - | - |
| Hartley, 1991 | Tegretol (Ciba-Geigy) Tablets | 12 | 0 | - | - | - | - | - | - |
| Carbamazepine (Ethical Generics) Tablets |  | 0 | - | - | - | - | - | - |
| Oles, 1992a | Tegretol (Ciba-Geigy) Tablets | 20 | 0 | - | - | - | - | - | - |
| Carbamazepine (Lemmon Co) Tablets |  | 0 | - | - | - | - | - | - |
| Oles 1992b | Tegretol (Ciba-Geigy) Tablets | 20 | 0 | - | - | - | - | - | - |
| Carbamazepine (Lemmon Co) Tablets |  | 0 | - | - | - | - | - | - |
| Reunanen, 1992 | Tegretol Retard (Ciba-Geigy) Tablets | 21 | 0 | - | - | - | - | - | - |
| Carbamazepine (Laakefarmos) Tablets |  | 0 | - | - | - | - | - | - |
| Silpakit, 1997 | Tegretol (Ciba-Geigy) Tablets | 18 | - | - | - | - | - | - | - |
| Carbamazepine (Central Poly) Tablets |  | - | - | - | - | - | - | - |
| Carbamazepine (Condrugs) Tablets |  | - | - | - | - | - | - | - |
| Carbamazepine (Pharmaland) Tablets |  | - | - | - | - | - | - | - |
| Aldenkamp, 1998 | Tegretol (Ciba-Geigy) Tablets | 12 | 0 | - | - | - | - | - | - |
| Generic (Pharmachemie) Tablets | 12 | 0 | - | - | - | - | - | - |
| Generic (Pharbita) Tablets | 12 | 0 | - | - | - | - | - | - |
| Garnett, 2005 | Tegretol (Novartis) Tablets | 275 | - | - | - | - | - | - | - |
| Generic (Various/Unspecified) Tablets | 705 | - | - | - | - | - | - | - |
| LeLorier, 2008d | Tegretol CR (manufacturer not reported) | 851 | - | - | - | - | - | - | - |
| Carbamazepine CR (manufacturer not reported) |  | - | - | - | - | - | - | - |
| Clobazam |
| Andermann, 2007b | Frisium (manufacturer not reported) | 1600 | - | - | - | - | - | - | - |
| Clobazam (manufacturers not reported) |  | - | - | - | - | - | - | - |
| LeLorier, 2008b | Frisium (manufacturer not reported) | 1060 | - | - | - | - | - | - | - |
| Clobazam (manufacturer not reported) |  | - | - | - | - | - | - | - |
| Gabapentin |
| LeLorier, 2008c | Neurontin (manufacturer not reported) | 202 | - | - | - | - | - | - | - |
| Gabapentin (manufacturer not reported) |  | - | - | - | - | - | - | - |
| Lamotrigine |
| Andermann, 2007a | Lamictal (GlaxoSmithKline) | 1142 | - | - | - | - | - | - | - |
| Lamotrigine (manufacturers not reported) |  | - | - | - | - | - | - | - |
| LeLorier, 2008a | Lamictal (GlaxoSmithKline)  | 449 | - | 8.24 visits per patient per year | 0.49 visits per patient per year | 3.29 days per patient per year | - | - | - |
| Lamotrigine (manufacturer(s) not reported) | 222 | - | 9.25 visits per patient per year | 0.56 visits per patient per year | 4.86 days per patient per year | - | - | - |
| Nielsen, 2008a | Lamictal (manufacturer not reported) | 9 | - | - | - | - | - | - | - |
| Lamotrigine (Copyform, Hexal, Ratiofarm, Ratiopharm, Farma, Actavis, Stada) |  | - | - | - | - | - | - | - |
| Levetiracetam, Oxcarbazepine, Phenobarbital or Primidone, Phenytoin |
| Lund, 1974 | Epanutin (Parke-Davis) capsules | 9 | 0 | - | - | - | - | - | - |
| Phenytoin sodium (Leo) capsules |  | 0 | - | - | - | - | - | - |
| Chen, 1982  | Epanutin (Parke-Davis) capsules | 18 | 0 | - | - | - | - | - | - |
| Phenytoin sodium (Boots) tablets |  | 0 | - | - | - | - | - | - |
| Phenytoin sodium (Cox) tablets |  | 0 | - | - | - | - | - | - |
| Phenytoin sodium (Kerfoot) tablet |  | 0 | - | - | - | - | - | - |
| Phenytoin sodium (McCarthy UK) tablets |  | 0 | - | - | - | - | - | - |
| Hodges, 1986 | Phenytoin (Parke-Davis) capsules | 19 | 0 | - | - | - | - | - | - |
| Phenytoin (Boots) tablets |  | 0 | - | - | - | - | - | - |
| Phenytoin (Evans) tablets |  | 0 | - | - | - | - | - | - |
| Kishore, 1986 | Dilantin (Parke-Davis, India) capsules  | 15 | 0 | - | - | - | - | - | - |
| Phenytoin (Epsolin, Cadila) tablets  | 15 | 0 | - | - | - | - | - | - |
| Phenytoin (Eptoin, Boots India) tablets  | 15 | 0 | - | - | - | - | - | - |
| Phenytoin (Epileptin, Indian Drugs and Pharmaceuticals) capsules | 15 | 0 | - | - | - | - | - | - |
| Mikati 1992a  | Dilantin (Parke-Davis) capsules | 10 | 0 | - | - | - | - | - | - |
| Phenytoin (Phenytex, manufacturer not reported) capsules |  | 0 | - | - | - | - | - | - |
| Soryal 1992a  | Epanutin (Parke-Davis) capsules | 14 | 0 | - | - | - | - | - | - |
| Phenytoin sodium (Evans) tablets |  | 0 | - | - | - | - | - | - |
| Phenytoin sodium (APS) tablets |  | 0 | - | - | - | - | - | - |
| Phenytoin sodium (Cox) tablets |  | 0 | - | - | - | - | - | - |
| Phenytoin sodium (Kerfoot) tablets |  | 0 | - | - | - | - | - | - |
| Phenytoin sodium (Regent) tablets |  | 0 | - | - | - | - | - | - |
| Topiramate |
| Duh, 2009 | Topamax (Ortho-McNeil) | 875 | - | 9.07 outpatient visits/person-year | 0.48 events/person-year | 2.55 days | - | - | - |
| Topiramate (Various manufacturers) – Single Product Users | 331 | - | 9.48outpatient visits/person-year | 0.52 events/person-year | 3.22 days | - | - | - |
| Topiramate (Various manufacturers) – Multiple Product Users | 99 | - | 8.74 outpatient visits/person-year | 0.83 events/person-year | 3.88 days | - | - | - |
| Paradis, 2009b | Topamax (Ortho-McNeil) | - | - | 9.0 outpatient visits/person-year | 0.5 events/person-year | 2.4 days | - | - | - |
| Topiramate (Various manufacturers) | - | - | 9.1 outpatient visits/person-year | 0.6 events/person-year | 3.1 days | - | - | - |
| Valproic Acid |
| Vadney, 1997 | Depakene (Abbott) | 64 | 0 | - | - | - | - | - | - |
| Valproic acid (Solvay) |  | 0 | - | - | - | - | - | - |
| Andermann, 2007c  | Depakene (manufacturer not reported) | 2017 | - | - | - | - | - | - | - |
| Valproic Acid (manufacturers not reported) |  | - | - | - | - | - | - | - |

aCrossover study

bReports on same database as Duh 2009

- = not reported; N = sample size; n = number of events; SD = standard deviation