Table F-2. Baseline characteristics of controlled studies comparing innovator versus generic antiepileptic drugs

| Study, Year | Group | N | Mean Age  (SD) | Male (%) | Body Weight (kg) | Race | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Caucasian (%) | Black (%) | Asian  (%) | Hispanic (%) | Other (%) |
| Unspecified Innovator and Brand Antiepileptic Drug Products | | | | | | | | | | |
| Rascati, 2009 | Cases | 991 | 35.6 (15.1) | 49.0 | - | - | - | - | - | - |
| Controls | 2973 | 35.6 (15.1) | 48.6 | - | - | - | - | - | - |
| Zachry, 2009 | Cases | 416 | 37.4 (14.8) | 45.0 | - | - | - | - | - | - |
| Controls | 1248 | 37.5 (14.7) | 44.2 | - | - | - | - | - | - |
| Devine, 2010 | Cases | 2949 | 42 | 43.9 | - | - | - | - | - | - |
| Controls | 8847 | 44 | 44.7 | - | - | - | - | - | - |
| Labiner, 2010a | Branded carbamazepine, gabapentin, phenytoin, primidone, zonisamide (manufacturer not reported) | 18,125 | 52.5 (16.0) | 47.6 | - | - | - | - | - | - |
| Carbamazepine, gabapentin, phenytoin, primidone, zonisamide (manufacturer not reported) |  |  |  |  |  |  |  |  |  |
| Labiner, 2010b | Branded carbamazepine, gabapentin, phenytoin, primidone, zonisamide (manufacturer not reported) | 15,500 | 49.1 (16.1) | 49.2 | - | - | - | - | - | - |
| Carbamazepine, gabapentin, phenytoin, primidone, zonisamide (manufacturer not reported) |  |  |  |  |  |  |  |  |  |

| Table F-2. Baseline characteristics of controlled studies comparing innovator versus generic antiepileptic drugs (continued) | | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Study, Year | Group | N | Mean Age  (SD) | Male (%) | Body Weight (kg) | Race | | | | |
| Caucasian (%) | Black (%) | Asian  (%) | Hispanic (%) | Other (%) |
| Carbamazepine | | | | | | | | | | |
| Kauko, 1974 | Tegretol (Ciba-Geigy) Tablets | 20 | 20 years (Range: 7 to 34) | 70.0 | - | - | - | - | - | - |
| Generic Carbamazepine (Laake Oy) Tablets |  |  |  |  |  |  |  |  |  |
| Glende, 1983 | Tegretol (Ciba-Geigy) Tablets | 5 | Range: 19-42 years | 80 | Range: 50-83 | - | - | - | - | - |
| Carbamazepine (AWD Dresden) Tablets |  |  |  |  |  |  |  |  |  |
| Jumao-as, 1989 | Tegretol (Ciba-Geigy) Tablets | 10 | Range: 34 – 70 Years | 100.0 | - | - | - | - | - | - |
| Generic Carbamazepine (Parke Davis) Tablets |  |  |  |  |  |  |  |  |  |
| Hartley, 1990 | Tegretol (Ciba-Geigy) | 23 | 10.7 (2.9) | 60.9 | 35.8 (11.8) | - | - | - | - | - |
| Carbamazepine (Ethical Generics) |  |  |  |  |  |  |  |  |  |
| Hartley, 1991 | Tegretol (Ciba-Geigy) Tablets | 12 | 10.6 (2.8) | 75.0 | - | - | - | - | - | - |
| Generic Carbamazepine (Ethical Generics) Tablets |  |  |  |  |  |  |  |  |  |
| Oles, 1992a | Tegretol (Ciba-Geigy) Tablets | 20 | 33.4 (15.4) | - | - | - | - | - | - | - |
| Carbamazepine (Lemmon Co) Tablets |  |  |  |  |  |  |  |  |  |
| Oles, 1992b | Tegretol (Ciba-Geigy) Tablets | 20 | 36.8 (16.2) | - | - | - | - | - | - | - |
| Carbamazepine (Lemmon Co) Tablets |  |  |  |  |  |  |  |  |  |
| Silpakit, 1997 | Tegretol (Ciba-Geigy) Tablets | 18 | 32.9 (9.1) | 50 | 53.9 (11.9) | - | - | - | - | - |
| Carbamazepine (Central Poly) Tablets |  |  |  |  |  |  |  |  |  |
| Carbamazepine (Condrugs) Tablets |  |  |  |  |  |  |  |  |  |
| Carbamazepine (Pharmaland) Tablets |  |  |  |  |  |  |  |  |  |
| Reunanen, 1992 | Tegretol Retard (Ciba-Geigy) Tablets | 20 | 42.7 (12.7) | 40 | - | - | - | - | - | - |
| Carbamazepine Slow Release (Laakefarmos) Tablets |  |  |  |  |  |  |  |  |  |
| Aldenkamp, 1998 | Tegretol (Ciba-Geigy) Tablets | 12 | 45.1 (10.6) | 58.3 | - | - | - | - | - | - |
| Carbamazepine (Pharmachemie) Tablets |  |  |  |  |  |  |  |  |  |
| Carbamazepine (Pharbita) Tablets |  |  |  |  |  |  |  |  |  |
| Garnett, 2005 | Tegretol (Novartis) Tablets | 275 | 40.6 (SE 0.8) | 41.1 | - | - | - | - | - | - |
| Generic (Various/Unspecified) Tablets | 705 | 43.5 (SE 0.6) | 40.0 | - | - | - | - | - | - |
| LeLorier, 2008d | Tegretol CR (manufacturer not reported) | 851 | 40 (17.3) | 50.6 | - | - | - | - | - | - |
| Carbamazepine CR (manufacturer not reported) |  |  |  |  |  |  |  |  |  |
| Clobazam | | | | | | | | | | |
| Andermann, 2007b | Frisium (manufacturer not reported) | 1600 | 38.5 (20.5) | 50.8 | - | - | - | - | - | - |
| Clobazam (manufacturers not reported) |  |  |  |  |  |  |  |  |  |
| LeLorier, 2008b  (N=1060) | Frisium (manufacturer not reported) | 1060 | 38 (18.5) | 47.4 | - | - | - | - | - | - |
| Clobazam (manufacturer not reported) |  |  |  |  |  |  |  |  |  |
| Gabapentin | | | | | | | | | | |
| LeLorier, 2008c | Neurontin (manufacturer not reported) | 202 | 49 (18.5) | 39.6 | - | - | - | - | - | - |
| Gabapentin (manufacturer not reported) |  |  |  |  |  |  |  |  |  |
| Lamotrigine | | | | | | | | | | |
| Andermann, 2007a | Lamictal (GlaxoSmithKline) | 1445 | 38.9 (20.8) | 46.5 | - | - | - | - | - | - |
| Lamotrigine (manufacturers not reported) |  |  |  |  |  |  |  |  |  |
| LeLorier, 2008 | Lamictal (GlaxoSmithKline) | 671 | 39 (18.7) | 43.8 | - | - | - | - | - | - |
| Lamotrigine (manufacturer(s) not reported) |  |  |  |  |  |  |  |  |  |
| Nielsen, 2008 | Lamictal (manufacturer not reported) | 9 | 43.8 (10.4) | 66.7 | - | - | - | - | - | - |
| Lamotrigine (Copyform, Hexal, Ratiofarm, Ratiopharm, Farma, Actavis, Stada) |  |  |  |  |  |  |  |  |  |
| Levetiracetam, Oxcarbazepine, Phenobarbital or Primidone, Phenytoin | | | | | | | | | | |
| Lund, 1974 | Epanutin (Parke-Davis) capsules | 9 | - | - | - | - | - | - | - | - |
| Phenytoin sodium (Leo) capsules |  |  |  |  |  |  |  |  |  |
| Chen, 1982 | Epanutin (Parke-Davis) capsules | 18 | - | - | - | - | - | - | - | - |
| Phenytoin sodium (Boots) tablets |  |  |  |  |  |  |  |  |  |
| Phenytoin sodium (Cox) tablets |  |  |  |  |  |  |  |  |  |
| Phenytoin sodium (Kerfoot) tablets |  |  |  |  |  |  |  |  |  |
| Phenytoin sodium (McCarthy UK) tablets |  |  |  |  |  |  |  |  |  |
| Hodges, 1986 | Phenytoin (Parke-Davis) capsules | 30 | 9.5 years of 30 initially enrolled | 60% of 30 initially enrrolled | - | - | - | - | - | - |
| Phenytoin (Boots) tablets |  |  |  |  |  |  |  |  |  |
| Phenytoin (Evans) tablets |  |  |  |  |  |  |  |  |  |
| Kishore, 1986 | Dilantin (Parke-Davis, India) capsules | 60 | 30.3 (11.3) | - | 55.4 (5.1)m  49 (7.5)f | - | - | - | - | - |
| Phenytoin (Epsolin, Cadila) tablets |  |  |  |  |  |  |  |  |  |
| Phenytoin (Eptoin, Boots India) tablets |  |  |  |  |  |  |  |  |  |
| Phenytoin (Epileptin, Indian Drugs and Pharmaceuticals) capsules |  |  |  |  |  |  |  |  |  |
| Mikati, 1992a | Dilantin (Parke-Davis) capsules | 10 | - | 54% of 13 enrolled | - | - | - | - | - | - |
| Phenytoin (Phenytex, manufacturer not reported) capsules |  |  |  |  |  |  |  |  |  |
| Soryal, 1992a | Epanutin (Parke-Davis) capsules | 14 | Range 18 to 67 years | 35% | All within 20% of IBW | - | - | - | - | - |
| Phenytoin sodium (Evans) tablets |  |  |  |  |  |  |  |  |  |
| Phenytoin sodium (APS) tablets |  |  |  |  |  |  |  |  |  |
| Phenytoin sodium (Cox) tablets |  |  |  |  |  |  |  |  |  |
| Phenytoin sodium (Kerfoot) tablets |  |  |  |  |  |  |  |  |  |
| Phenytoin sodium (Regent) tablets |  |  |  |  |  |  |  |  |  |
| Topiramate | | | | | | | | | | |
| Duh, 2009  (N=948) | Topamax (Ortho-McNeil) | 875 | 34.5 (17.0) | 39.3% | - | - | - | - | - | - |
| Topiramate (Various manufacturers) – Single Product Users | 331 | 37.5 (16.1) | 41.4% | - | - | - | - | - | - |
| Topiramate (Various manufacturers) – Multiple Product Users | 99 | 33.7 (14.7) | 32.3% | - | - | - | - | - | - |
| Paradis, 2009b  (N=1164) | Topamax (Ortho-McNeil)  Topiramate (Various manufacturers) | 1164 | 39.8 (17.2) | 38.3% | - | - | - | - | - | - |
| Valproic Acid | | | | | | | | | | |
| Vadney, 1997 | Depakene (Abbott) | 64 | 39.6 (Range 17 to 72) | - | 59.6 kg (Range 35 to 94) | - | - | - | - | - |
| Valproic acid (Solvay) |  |  |  |  |  |  |  |  |  |
| Andermann, 2007c | Depakene (manufacturer not reported) | 2017 | 44.4 (18.2) | 48.0 | - | - | - | - | - | - |
| Valproic Acid (manufacturers not reported) |  |  |  |  |  |  |  |  |  |

- = not reported; IBW = ideal body weight; f = value for females; kg = kilograms; N = sample size; m = value for males; SD = standard deviation aCrossover Study bReports on same database as Duh 2009