



Market Share of Generic AEDs^{1,2} in States Requiring and Not Requiring F

Year		Count and Percentage of Scripts in States <u>Not</u> Requiring Notification/Consent for Substitution of AED		
		Count of Brand Scripts	Brand Market Share	Count of Generic Scripts
2000	Yearly Total	158,972	47.7%	174,319
2001	Yearly Total	301,637	46.1%	353,339
2002	Yearly Total	398,294	46.8%	453,008
2003	Yearly Total	520,763	47.6%	572,478
2004	Yearly Total	523,477	45.3%	630,830
2005	Yearly Total	411,449	30.4%	943,986
2006	Yearly Total	453,066	29.7%	1,073,754
2007	Yearly Total	446,882	29.4%	1,072,782
2008	Yearly Total	347,481	25.3%	1,026,085
2009	Yearly Total	162,871	10.8%	1,340,022
2010	Yearly Total	126,158	7.0%	1,669,693
2011	Yearly Total	89,072	5.3%	1,600,523
2012	Yearly Total	76,260	4.4%	1,655,585
Q1 2013	Quarterly Total	14,377	3.9%	352,569
2000-Q1 2013	Total	4,030,759	23.8%	12,918,973

Notes:

[1] Market share for generic AEDs was calculated as the proportion of generic AEDs scripts to

[2] The following branded AEDs were not considered because they did not have a generic equivalent marketed during this timeframe): Banzel, Celantin, Fycompa, Horizant, Lyrica, Mesantoin, Trokendi XR, and Vimpat.

[3] The list of states requiring prescriber notification/consent for AED substitution is as follows:

<u>State</u>	<u>Date Law Passed</u>
Hawaii	June 17, 1996
North Carolina	July 1, 1997
Tennessee	July 1, 2007
Utah	May 5, 2008
Idaho	July 1, 2010
Connecticut	October 1, 2011

[4] States requiring prescriber notification or consent for AED substitution contributed script counts prior to the date of the specific legislation implementing the notification or consent requirement

Prescriber Notification/Consent for AED Substitution Between 2000 - Q1 2013

Count and Percentage of Scripts in States Requiring Prescriber Notification/Consent for Substitution of AEDs ³⁻⁴				
Generic Market Share	Count of Brand Scripts	Brand Market Share	Count of Generic Scripts	Generic Market Share
52.3%	9,846	46.8%	11,200	53.2%
53.9%	12,296	47.8%	13,419	52.2%
53.2%	15,207	47.8%	16,607	52.2%
52.4%	21,801	46.4%	25,174	53.6%
54.7%	22,112	44.1%	28,059	55.9%
69.6%	14,770	28.9%	36,421	71.1%
70.3%	15,544	28.9%	38,175	71.1%
70.6%	19,130	27.9%	49,333	72.1%
74.7%	15,595	23.6%	50,395	76.4%
89.2%	7,895	10.5%	67,588	89.5%
93.0%	6,689	6.8%	91,510	93.2%
94.7%	5,271	5.2%	95,817	94.8%
95.6%	6,316	4.9%	123,895	95.1%
96.1%	1,238	4.4%	26,980	95.6%
76.2%	173,710	20.5%	674,573	79.5%

the total number of generic and branded AED scripts combined.
 ivalent with final approval during this timeframe (or, in the case of Lyrica, we know that no generics
 , Milontin, Onfi, Oxtellar XR, Paradione, Phenurone, Potiga, Preganone, Sabril, Stavzor, Tridione,

Law Summary

- Prescriber consent required before AED substitution. Haw. Rev. Stat. § 328-92(c).
 - Prescriber consent required before substitution of certain AEDs. N.C. Gen. Stat. Ann. §§ 90-85.27 (4a), 90-85.28 (b1). See also "Narrow Therapeutic Index Drugs Designated by the North Carolina Secretary of Human Resources," North Carolina Register, Vol. 27(13) (Jan. 2, 2013), at 1263, at <http://www.ncoah.com/rules/register/Volume27IssueJanuary22013.pdf>.
 - Prescriber notification required before AED substitution. Tenn. Code Ann. § 53-10-210(b).
 - ED substitution is permitted if pharmacist cannot dispense as written and notifies prescriber before substitution. Utah Code Ann. § 58-17b-605(8)(c).
 - Prescriber notification required after AED substitution. Idaho Code Ann. § 54-1770(2).
 - Prescriber consent required before AED substitution. Conn. Gen. Stat. § 20-619(i).
- unts to the group of states not requiring prescriber notification or consent for AEDs substitution,
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ANTI-EPILEPTIC DRUGS (AEDs) WITH GENERICS			
BRAND	GENERIC		
Brand Name (Trade Name)	Generic Name (Active Ingredient)	First Generic Entry Date ¹	First Generic Manufacturer
ANTI-EPILEPTIC DRUGS WITH GENERIC ENTRY BETWEEN 2000 AND Q1 2013			
Magnesium Sulfate Magnesium Sulfate In Plastic Container Magnesium Sulfate In Dextrose 5% In Plastic Container	Magnesium Sulfate	April 25, 2000	Hospira Inc
Depacon	Valproate Sodium	November 14, 2002	Bedford Laboratories Div Ben Venue Laboratories Inc
Neurontin Gralise	Gabapentin	September 12, 2003	Actavis Elizabeth LLC
Zonegran	Zonisamide	December 22, 2005	Mutual Pharmaceutical Co Inc
Lamictal Lamictal CD Lamictal ODT	Lamotrigine	June 21, 2006	Teva Pharmaceuticals USA Inc
Carebyx	Fosphenytoin Sodium	August 6, 2007	Teva Pharmaceuticals USA Inc
Trileptal	Oxcarbazepine	October 9, 2007	Sun Pharmaceutical Industries Ltd
Depakote Depakote CP	Divalproex Sodium (Delayed Release)	July 29, 2008	Teva Pharmaceuticals USA Inc
Keppra	Levetiracetam	November 4, 2008	Mylan Pharmaceuticals Inc
Diamox (Extended Release) ²	Acetazolamide (Extended Release)	December 10, 2008	Zydus Pharmaceuticals USA Inc
Depakote ER	Divalproex Sodium (Extended Release)	January 29, 2009	Mylan Pharmaceuticals Inc
Topamax Topamax Sprinkles	Topiramate	March 27, 2009	Roxane Laboratories Inc
Tegretol-XR Carbatrol Equetro	Carbamazepine (Extended Release)	March 31, 2009	Taro Pharmaceutical Industries Inc
Keppra (Injection) Levetiracetam In Sodium Chloride	Levetiracetam (Injection)	May 26, 2010	Fresenius Kabi USA LLC
Keppra XR	Levetiracetam (Extended Release)	September 12, 2011	Watson Laboratories Inc
Felbatol	Felbamate	September 13, 2011	Teva Pharmaceuticals USA Inc
Gabitril	Tiagabine Hydrochloride	November 4, 2011	Sun Pharmaceutical Industries Ltd
Lamictal XR	Lamotrigine (Extended Release)	December 26, 2012	Anchen Pharmaceuticals Inc
ANTI-EPILEPTIC DRUGS WITH GENERIC ENTRY PRIOR TO JANUARY 2000			
Dilantin-30 Dilantin-125	Phenytoin	Approved Prior to Jan 1, 1982	Pfizer Pharmaceuticals Ltd
Dilantin Diphenylan Sodium Prompt Phenytoin Sodium Phenytek Extended Phenytoin Sodium Phenytek	Phenytoin Sodium	Approved Prior to Jan 1, 1982	Hikma Maple Ltd
Mysoline	Primidone	Approved Prior to Jan 1, 1982	Watson Laboratories Inc
Diamox ²	Acetazolamide	Approved Prior to Jan 1, 1982	Aira Laboratories Inc
Valium Valrelease Q-Pam Diazepam Intensol Dizac Diastat Diastat Acudial	Diazepam	September 4, 1985	Warner Chilcott Div Warner Lambert Co
Ativan Loraz Lorazepam Intensol Lorazepam Preservative Free	Lorazepam	December 10, 1985	Mutual Pharmaceutical Co Inc
Depakene	Valproic Acid	February 28, 1986	Par Pharmaceutical Inc
Tegretol	Carbamazepine	May 15, 1986	USL Pharma Inc
Tranxene	Clonazepam Dipotassium	June 23, 1987	USL Pharma Inc
Zarontin	Ethosuximide	July 30, 1993	Teva Pharmaceuticals USA Inc
Diamox (Injection) ²	Acetazolamide Sodium	February 28, 1995	Bedford Laboratories Div Ben Venue Laboratories Inc
Klonopin Klonopin Rapidly Disintegrating	Clonazepam	September 10, 1996	Teva Pharmaceuticals USA Inc
Notes:			
[1] Generic approval date is used as a proxy for generic entry date.			
[2] Diamox drug label: Diamox has utility as an adjuvant treatment of certain dysfunctions of the central nervous system (e.g. epilepsy). Included in the list provided by NYU Comprehensive Epilepsy Center.			
Sources:			
• FDA's "Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations," available at http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm .			
• New York University NYU Comprehensive Epilepsy Center, "Medications," at http://epilepsy.med.nyu.edu/diagnosis-treatment/medications#thash.ITMRqyV.dpbs .			
• Medi-Span's Master Drugs Database, at http://www.medispan.com/master-drug-database.aspx (we selected from this commercial database Generic Product Identifier Codes associated with anticonvulsants).			
• Pharamproje, at http://www.citeline.com/products/pharamproje/ (we selected from this commercial database drugs with the therapy code corresponding to Anticonvulsants, Antiepileptics, and Epilepsy).			