

**Memorandum**

**Department of Health and Human Services  
Public Health Service  
Food and Drug Administration  
Center for Drug Evaluation and Research**

**PID#:** A060090-D050194

**DATE:** June 1, 2006

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**THROUGH:** Solomon Iyasu, M.D., M.P.H., Acting Director  
Division of Surveillance, Research and Communication Support, HFD-410

**TO:** M. Dianne Murphy, M.D.  
Director, Office of Pediatric Therapeutics (OPT), OIASI  
Office of the Commissioner

**SUBJECT:** One Year Post-Pediatric Exclusivity Post-marketing Adverse Event Review: Drug Use Data  
Trileptal<sup>®</sup> (oxcarbazepine) Tablets: NDA 21-014  
Trileptal<sup>®</sup> (oxcarbazepine) Oral Suspension: NDA 21-285  
Pediatric Exclusivity Grant Date: March 2, 2005

**\*\*This document contains proprietary drug use data obtained by FDA under contract. The drug use data/information cannot be released to the public/non-FDA personnel without contractor approval obtained through the FDA/CDER Office of Surveillance and Epidemiology.\*\***

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**EXECUTIVE SUMMARY**

This consult examines drug utilization trends for oral tablet and suspension formulations of Trileptal<sup>®</sup> (oxcarbazepine) in the pediatric population (ages 0-16 years), with primary focus on patterns of use one year before and one year following the granting of Pediatric Exclusivity on March 2, 2005. Proprietary drug use databases licensed by the Agency were used to conduct this analysis. IMS Health, IMS National Sales Perspective<sup>™</sup> data were used to determine the various retail and non-retail channels of distribution. We examined the utilization patterns for Trileptal<sup>®</sup> focusing on the outpatient setting. Outpatient drug use data were derived from IMS Health, National Disease and Therapeutic Index<sup>™</sup> (NDTI<sup>™</sup>), as well as from Verispan, LLC, Vector One<sup>®</sup>: National (VONA). Outpatient drug utilization patterns were examined for the three 12-month periods from April 1, 2003 through March 31, 2006.

Among the eight selected anticonvulsants (oxcarbazepine, carbamazepine, zonisamide, lamotrigine, topiramate, levetiracetam, phenobarbital, and phenytoin) analyzed, Trileptal<sup>®</sup> ranked sixth in terms of the number of prescriptions dispensed nationwide, accounting for approximately 9% of all dispensed prescriptions.

The number of outpatient prescriptions dispensed for Trileptal<sup>®</sup> (oxcarbazepine) increased by approximately 2% from 2,702,000 prescriptions dispensed during the pre-exclusivity period (April 2004 – March 2005) to approximately 2,750,000 prescriptions dispensed during the post-exclusivity period (April 2005 to March 2006). A larger growth (12%) in dispensed prescriptions was noticed when comparing the 12-month period two years prior to the granting of pediatric exclusivity (April 2003 to March 2004) to the one year prior to the granting of exclusivity (April 2004 to March 2005).

Dispensed prescriptions for Trileptal<sup>®</sup> to the pediatric population aged 0-16 years accounted for approximately 27% - 28% of the total prescriptions dispensed during the three 12-month periods of this analysis. The total number of prescriptions dispensed for Trileptal<sup>®</sup> to the pediatric population aged 0-16 years increased by approximately 17% from the two years prior to the granting of pediatric exclusivity (April 2003-March 2005) to the post-exclusivity period (April 2005-March 2006).

Neurologists were the most frequent prescriber specialty associated with Trileptal<sup>®</sup> during all three time periods of this analysis, accounting for approximately 25% of all dispensed prescriptions. Pediatricians accounted for approximately 3% of all dispensed prescriptions for Trileptal<sup>®</sup> during the same time period.

The most common diagnosis associated with a mention of Trileptal<sup>®</sup> for patients aged 0-16 years during office-based physician-patient encounters was “convulsions” (ICD-9 code 780.3), accounting for almost 30% of the mentions during the post-exclusivity period. “Bipolar affective disorder, unspecified” (ICD-9 code 296.7) was the second most commonly mentioned diagnosis (22% of mentions) in the pediatric population.

## INTRODUCTION

On January 4, 2002, Congress enacted the Best Pharmaceuticals for Children Act (BPCA) to improve the safety and efficacy of pharmaceuticals for children. Section 17 of that Act requires the reporting of adverse events associated with the use of a drug during the one year following the date on which the drug received marketing exclusivity. In support of this mandate, the FDA is required to provide a report to the Pediatric Advisory Committee on the drug utilization patterns and adverse events associated with the use of the drug. This review is in addition to the routine post-marketing safety surveillance activities the FDA performs for all marketed drugs.

Trileptal<sup>®</sup> (oxcarbazepine) 150 mg, 300 mg, and 600 mg tablets (NDA 21-014) was approved on January 14, 2000, and Trileptal<sup>®</sup> Oral Suspension 300 mg/5 mL (NDA 21-285) was approved on May 25, 2001, as monotherapy or adjunctive therapy in the treatment of partial seizures in adults with epilepsy, and as adjunctive therapy in the treatment of partial seizures in children ages 4-16 with epilepsy. On August 7, 2003, both formulations were approved for use as monotherapy in the treatment of partial seizures in children ages 4-16.

The Pediatric Exclusivity Board of the FDA granted pediatric exclusivity for Trileptal<sup>®</sup> (oxcarbazepine) Tablets and Trileptal<sup>®</sup> (oxcarbazepine) Oral Suspension on March 2, 2005. On October 28, 2005, both formulations were approved for use as adjunctive therapy in the treatment of partial seizures in children with epilepsy aged 2 to 4 years under NDA 21-014/S-013 and NDA 21-285/S-008. This review describes outpatient drug use patterns for all forms of Trileptal<sup>®</sup> in the pediatric (ages 0-16 years) and adult (ages 17 years and older) population in the years before and after granting the pediatric exclusivity. Proprietary drug use databases licensed by the Agency were used to conduct this analysis.

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## METHODS

### Setting of Use

IMS Health, National Sales Perspectives<sup>™</sup> data (see Appendix) were used to determine the setting in which Trileptal<sup>®</sup> (oxcarbazepine) was sold. Sales of this product by number of bottles of oral tablets and oral solution sold from the manufacturer to various retail channels of distribution were analyzed for three 12-month time periods from January 1, 2003 through December 31, 2005. The data suggest that 80% of Trileptal<sup>®</sup> sales in the U.S. were distributed through retail sales channels (data not shown). Mail order pharmacies, included in the retail sales channel accounted for an estimated 15% of total Trileptal<sup>®</sup> sales throughout the time period examined<sup>1</sup>.

We therefore examined the utilization patterns for Trileptal<sup>®</sup> (oxcarbazepine) focusing on the outpatient setting. Outpatient drug use was derived from the IMS Health, National Disease and Therapeutic Index<sup>™</sup> (NDTI<sup>™</sup>) as well as from Verispan, LLC, Vector One<sup>®</sup>: National (VONA) (see Appendix). For the purpose of providing a broad perspective on Trileptal in anticonvulsant therapy, we compared its utilization to that of seven other anticonvulsant drugs, including carbamazepine, zonisamide, lamotrigine, topiramate, levetiracetam, phenobarbital, and

phenytoin. Throughout our analysis, we used the Agency's cut-off age definition of a pediatric patient (age 0-16 years). Three 12-month time periods from April 1, 2003 through March 31, 2006 were analyzed.

## **RESULTS**

### **A. Outpatient Drug Use**

#### **I. Dispensed Prescriptions**

Outpatient prescriptions dispensed for the eight selected anticonvulsants combined (oxcarbazepine, carbamazepine, zonisamide, lamotrigine, topiramate, levetiracetam, phenobarbital, and phenytoin) increased by approximately 5% from 29.9 million dispensed prescriptions in the pre-exclusivity period (April 2004 to March 2005) to 31.3 million dispensed prescriptions in the post-exclusivity period (April 2005 to March 2006) (Table 1). Among the eight selected anticonvulsants, Trileptal<sup>®</sup> ranked sixth in terms of the number of prescriptions dispensed nationwide, accounting for approximately 9% of all dispensed prescriptions in this analysis.

The number of outpatient prescriptions dispensed for Trileptal<sup>®</sup> (oxcarbazepine) increased by approximately 2% from 2,702,000 prescriptions dispensed during the pre-exclusivity period (April 2004 – March 2005) to approximately 2,750,000 prescriptions dispensed during the post-exclusivity period (April 2005 to March 2006) (Table 1). A larger growth (12%) in dispensed prescriptions was noticed when comparing the 12-month period two years prior to the granting of pediatric exclusivity (April 2003 to March 2004) to the one year prior to the granting of exclusivity (April 2004 to March 2005).

**Table 1. Total Number of Prescriptions Dispensed in Retail Pharmacies Nationwide for Selected Anti-Seizure Agents During Specified 1-year Intervals, April 2003-March 2006, Verispan LLC: VONA**

	April 2003-March 2004		April 2004-March 2005		April 2005-March 2006	
	N*	%	N*	%	N*	%
<b>Selected Anti-Seizure Agents</b>	<b>28,288,000</b>	<b>100.0</b>	<b>29,946,000</b>	<b>100.0</b>	<b>31,318,000</b>	<b>100.0</b>
Phenytoin	7,360,000	26.0	7,009,000	23.4	6,663,000	21.3
Topiramate (Topamax®)	4,963,000	17.5	5,561,000	18.6	6,226,000	19.9
Carbamazepine	5,842,000	20.7	5,478,000	18.3	5,212,000	16.6
Phenobarbital	3,156,000	11.2	3,066,000	10.2	2,954,000	9.4
Lamotrigine (Lamictal®)	2,669,000	9.4	3,739,000	12.5	4,796,000	15.3
<b>Oxcarbazepine (Trileptal®)</b>	<b>2,410,000</b>	<b>8.5</b>	<b>2,702,000</b>	<b>9.0</b>	<b>2,750,000</b>	<b>8.8</b>
<b>Tablets</b>	<b>2,304,000</b>	<b>95.6</b>	<b>2,553,000</b>	<b>94.5</b>	<b>2,569,000</b>	<b>93.4</b>
<b>Suspension</b>	<b>106,000</b>	<b>4.4</b>	<b>149,000</b>	<b>5.5</b>	<b>181,000</b>	<b>6.6</b>
Levetiracetam (Keppra®)	1,206,000	4.3	1,544,000	5.2	1,869,000	6.0
Zonisamide (Zonegran®)	681,000	2.4	846,000	2.8	848,000	2.7

Verispan, LLC, April 2003- March 2006 Data Extracted May 2006 (File: A060090 5-16-06 oxcarbazepine.qry)

\*Numbers are rounded to thousands - Subtotals may not sum exactly due to rounding

## II. Prescriber Specialty

Neurology was the prescriber specialty most frequently associated with dispensed prescriptions for Trileptal® (oxcarbazepine), accounting for nearly one-quarter of the total prescriptions dispensed during the three 12-month time periods (Table 2). General Practitioners, including general practice, family practice, and osteopathic physicians, accounted for an estimated 6% of the dispensed prescriptions for Trileptal® during the post-exclusivity period (April 2005 – March 2006). Pediatrics accounted for approximately 3% of all dispensed prescriptions for Trileptal® in the post-exclusivity period. The proportion of all other provider specialties prescribing Trileptal® in the outpatient setting showed no substantial change during the 36-month analysis period.

**Table 2. Total Number of Prescriptions Dispensed for Trileptal® (all dosage forms) Nationwide by Physician Specialty During Specified 1-year Intervals, April 2003-March 2006, Verispan LLC: VONA**

Prescriber Specialty	April 2003-March2004		April 2004-March2005		April 2005-March2006	
	N *	%	N *	%	N *	%
<b>All Prescriber Specialties</b>	<b>2,410,000</b>	<b>100.0</b>	<b>2,702,000</b>	<b>100.0</b>	<b>2,750,000</b>	<b>100.0</b>
Neurology	596,000	24.7	653,000	24.2	726,000	26.4
Unspecified	346,000	14.4	487,000	18.0	366,000	13.3
GP/FM/DO	104,000	4.3	129,000	4.8	156,000	5.7
Internal Medicine	69,000	2.8	82,000	3.0	97,000	3.5
Pediatrics	52,000	2.2	64,000	2.4	77,000	2.8
Other Specialties	1,244,000	51.6	1,287,000	47.6	1,329,000	48.3

Verispan, LLC, April 2003- March 2006 Data Extracted May 2006 (File: A060090 5-16-06 oxcarbazepine MD.qry)

\* Numbers are rounded to thousands - Subtotals may not sum exactly due to rounding

### III. Patient Demographics

Prescriptions dispensed for Trileptal® (oxcarbazepine) to the pediatric population aged 0-16 years increased by approximately 1% from roughly 754,000 prescriptions dispensed in the pre-exclusivity period (April 2004 – March 2005) to approximately 763,000 prescriptions dispensed in the post-exclusivity period (April 2005 – March 2006) (Table 3). Similar to dispensed prescription data for the overall population, a larger growth (17%) in dispensed prescriptions for the pediatric population occurred when comparing the 12-month period two years prior to the granting of pediatric exclusivity on March 2005 to the post-exclusivity period. Dispensed prescriptions of Trileptal® to the pediatric population aged 0-16 years accounted for approximately 27% - 28% of the total dispensed Trileptal® prescriptions during all three-year time periods observed. Trileptal® tablets dosage form accounted for the majority of the prescriptions for the pediatric population. The proportion of dispensed prescriptions for the oral suspension dosage form of Trileptal® in the 0-16 year age group grew from 15.3% to 17.9% to 21.3% over the three 12-month time periods observed.

**Table 3. Outpatient Prescriptions Dispensed for Trileptal® by Age Groups During April 2003- March 2006, Verispan LLC: VONA**

	April 2003-March2004		April 2004-March2005		April 2005-March2006	
	N*	%	N*	%	N*	%
<b>Total</b>	<b>2,410,000</b>	<b>100.0</b>	<b>2,702,000</b>	<b>100.0</b>	<b>2,750,000</b>	<b>100.0</b>
<b>Age 0-16</b>	<b>647,000</b>	<b>26.8</b>	<b>754,000</b>	<b>27.9</b>	<b>763,000</b>	<b>27.7</b>
<b>Tablets</b>	<b>548,000</b>	<b>84.7</b>	<b>619,000</b>	<b>82.1</b>	<b>600,000</b>	<b>78.7</b>
<b>Suspension</b>	<b>99,000</b>	<b>15.3</b>	<b>135,000</b>	<b>17.9</b>	<b>163,000</b>	<b>21.3</b>
<b>Age 17+</b>	<b>1,738,000</b>	<b>72.1</b>	<b>1,883,000</b>	<b>69.7</b>	<b>1,924,000</b>	<b>69.9</b>
<b>Unspecified</b>	<b>25,000</b>	<b>1.0</b>	<b>65,000</b>	<b>2.4</b>	<b>64,000</b>	<b>2.3</b>

Verispan, LLC, April 2003- March 2006 Data Extracted May 2006 (File: A060090 5-16-06 oxcarbazepine Age.qry)

\* Numbers are rounded to thousands - Subtotals may not sum exactly due to rounding

According to data from Verispan’s Total Patient Tracker, over the 3 years of this analysis, the estimated number of patients receiving a Trileptal® prescription has remained relatively stable (Table 4). The number of patients aged 0-16 years that received a Trileptal® prescription increased approximately 7% between April 2003-March 2004 and April 2004-March 2005 before pediatric exclusivity was granted, and decreased approximately 4% from April 2004-March 2005 to April 2005-March 2006 after pediatric exclusivity was granted.

**Table 4. The Projected Number of Unique Patients Receiving a Prescription for Trileptal® From Retail Pharmacies, April 2003- March 2006, Verispan LLC: TPT**

	April 2003-March2004		April 2004-March2005		April 2005-March2006	
	Patient Count	%	Patient Count	%	Patient Count	%
Grand Total	587,089	100.0%	597,960	100.0%	586,293	100.0%
0 - 16	148,628	25.3%	159,959	26.8%	153,878	26.3%
17+	436,790	74.4%	427,263	71.5%	422,841	72.1%
UNKNOWN AGE	13,584	2.3%	31,917	5.3%	30,132	5.1%

Verispan, LLC Total Patient Tracker, 2003-2005, Data Extracted February 2006 (File: A060064-D040850 Zofran BPCA Custom Age Report.xls)

\* Subtotals may not sum exactly due to rounding error

#### IV. Indications for Use

The two most common diagnoses associated with a mention of Trileptal® (oxcarbazepine) for adults during office-based physician-patient encounters were “bipolar affective disorder, unspecified” (ICD-9 code 296.7) and “convulsions” (ICD-9 code 780.3), accounting for approximately 21.5% and 13.4% of mentions, respectively, during the post-exclusivity period (Table 5). The most common diagnosis mentioned for patients aged 0-16 years old was “convulsions” (ICD-9 code 780.3), accounting for approximately 19% and 30% of the mentions in the pediatric population during the pre- and the post-exclusivity time periods, respectively. “Bipolar affective disorder, unspecified” (ICD-9 code 296.7) was the second most commonly mentioned diagnosis in the pediatric population during all time periods analyzed.

**Table 5. Top Three Diagnoses Associated with Mentions of Trileptal® for the Pediatric and Adult Population, April 2003- March 2006, IMS Health, National Disease and Therapeutic Index™**

	April 2003- March2004		April 2004- March2005		April 2005- March2006	
IMS Reported ICD-9 Codes	N*	%	N	%	N	%
<b>Trileptal® Total Mentions</b>	<b>1,233,000</b>	<b>100.0</b>	<b>1,354,000</b>	<b>100.0</b>	<b>1,340,000</b>	<b>100.0</b>
<b>Age 17+ Years</b>	<b>936,000</b>	<b>75.9</b>	<b>919,000</b>	<b>67.9</b>	<b>952,000</b>	<b>71.1</b>
296.7 Bipolar Affect. Disorder, Unspec.	155,000	16.5	159,000	17.3	204,000	21.5
780.3 Convulsions	120,000	12.8	151,000	16.5	128,000	13.4
345.9 Epilepsy, Unspec.	66,000	7.1	53,000	5.8	92,000	9.7
Other Diagnoses (101)	595,000	63.8	555,000	60.0	528,000	55.0
<b>Age 1-16 Years</b>	<b>250,000</b>	<b>20.3</b>	<b>395,000</b>	<b>29.2</b>	<b>335,000</b>	<b>25.0</b>
780.3 Convulsions	49,000	19.6	75,000	18.9	100,000	29.9
296.7 Bipolar Affect. Disorder, Unspec.	61,000	24.4	94,000	23.7	73,000	21.7
345.9 Epilepsy, Unspec.	23,000	9.3	18,000	4.7	46,000	13.7
Other Diagnoses (37)	117,000	47.0	208,000	53.0	116,000	35.0
<b>Unspecified</b>	<b>47,000</b>	<b>3.8</b>	<b>40,000</b>	<b>3.0</b>	<b>53,000</b>	<b>3.9</b>

IMS Health, National Disease and Therapeutic Index™ CD-ROM, NDTI 3 year. April 2003-March 2006. Data extracted May 2006 (File: 0605trileptaldiag.dvf)

\*rounded to thousands

## DISCUSSION

Based on the databases used for this consult, the use of the 8 selected anticonvulsants (oxcarbazepine, carbamazepine, zonisamide, lamotrigine, topiramate, levetiracetam, phenobarbital, and phenytoin) has not changed significantly from the pre- to the post-exclusivity periods (April 2004 to March 2006). The total number of dispensed prescriptions for Trileptal® (oxcarbazepine) was also steady from the pre- to the post-exclusivity periods. The use of Trileptal® in the pediatric population aged 0-16 years appears to have increased somewhat over this period, yet the majority of Trileptal® product utilization was in adults.

According to the American Academy of Neurology (AAN) guidelines on the new-onset epilepsy treatment in adults and children, the use of both recently introduced antiepileptic drugs (AEDs: gabapentin, lamotrigine, topiramate, and oxcarbazepine) and standard agents (carbamazepine, phenytoin, valproic acid/divalproex, and phenobarbital) is recommended.<sup>2</sup> In addition, all of the new AEDs were found to be appropriate for adjunctive treatment of refractory partial seizures in adults and children.<sup>3</sup> In contrast, the British institute, National Institute for Health and Clinical Excellence (NICE), recommends using a tiered approach in which the newer AEDs (lamotrigine, topiramate, and oxcarbazepine) are used only by patients who derive no benefit from the older antiepileptic agents, such as carbamazepine and sodium valproate.<sup>4</sup>

Although Trileptal® is indicated for the treatment of seizures, data from IMS Health suggest that bipolar disorder is a frequently mentioned diagnosis associated with the use of Trileptal® for the overall population during office-based physician-patient encounters over the three 12-month periods analyzed. Bipolar disorder is not a labeled use for Trileptal®. A number of studies that examined the use of oxcarbazepine point to its potential effectiveness in the treatment of bipolar disorder due to improved tolerability and fewer drug-drug interactions compared to other antiepileptic agents.<sup>5,6,7</sup> Although some studies show that oxcarbazepine has some effectiveness in treating bipolar disorders, other studies convey their data as preliminary and cite the need for more large-scale studies.<sup>8,9</sup>

Findings from this consult should be interpreted in the context of the known limitations of the databases used. We estimated that the use of Trileptal® was mostly in the outpatient settings based on IMS Health, IMS National Sales Perspectives™ data. These data do not provide a direct estimate of use but do provide a national estimate of units sold from the manufacturer to various channels of distribution. The amount of product purchased by these retail and non-retail channels of distribution may be a possible surrogate for use, if we assume that facilities purchase drugs in quantities reflective of actual patient use.

NDTI™ data provide estimates of patient demographics and indications for use of medicinal products in the U.S. Due to the sampling and data collection methodologies, the small sample size can make these data unstable, particularly when use is not common in the pediatric population.

## CONCLUSION

In summary, Trileptal® (oxcarbazepine) usage in the pediatric and adult population has increased somewhat over the past three years, yet the total dispensed prescriptions for Trileptal® has not changed significantly from the pre- to the post-exclusivity periods (April 2004 to March 2006). Dispensed prescriptions for Trileptal® for pediatric patients aged 0-16 years increased by approximately 17% from the 12-month period two years prior to the granting of pediatric exclusivity (April 2003 to March 2004) to the one year prior to the granting of exclusivity (April 2004 to March 2005). Pediatric patients aged 0-16 accounted for approximately 28% of the total dispensed prescriptions during April 2005 – March 2006 with the oral tablet dosage form most commonly prescribed to this age group. Prescriptions written by pediatricians accounted for an estimated 3% of all Trileptal® prescriptions dispensed in the post-exclusivity period.

## APPENDIX

### ***IMS HEALTH, IMS NATIONAL SALES PERSPECTIVES™***

IMS Health National Sales Perspectives™ measures the volume of drug products (both prescription and over-the-counter) and selected diagnostic products moving from manufacturers into various outlets within the retail and non-retail markets in terms of sales dollars, vials, and market share. Outlets within the retail market include the following pharmacy settings: chain drug stores, independent drug stores, mass merchandisers, food stores, and mail service. Outlets within the non-retail market include clinics, non-federal hospitals, federal facilities, HMOs, long-term care facilities, home health care, and other miscellaneous settings. These data are projected nationally to reflect national drug sales patterns.

For this analysis, the sales trends of Trileptal® were examined from January 1, 2003 – December 31, 2005 inclusive.

### ***VERISPAN, LLC***

Vector One®: National (VONA)

Verispan's VONA measures retail dispensing of prescriptions or the frequency with which drugs move out of retail pharmacies into the hands of consumers via formal prescriptions. Information on the physician specialty, the patient's age and gender, and estimates for the numbers of patients that are continuing or new to therapy are available.

The Vector One® database integrates prescription activity from a variety of sources including national retail chains, mass merchandisers, pharmacy benefits managers and their data systems, and provider groups. Vector One™ receives over 1.8 billion prescription claims, representing over 150 million unique patients.

The number of dispensed prescriptions is obtained from a sample of virtually all retail pharmacies throughout the U.S and represents approximately half of the retail prescriptions dispensed nationwide. Verispan receives all prescriptions from approximately one-third of the stores and a significant sample of prescriptions from the remaining stores.

Data for this analysis included prescriptions dispensed for miscellaneous anticonvulsants including Trileptal® from April 1, 2003 – March 31, 2006 inclusive.

### ***VERISPAN, LLC***

Vector One®: Total Patient Tracker (TPT)

Verispan's Total Patient Tracker is a national-level projected audit designed to estimate the total number of unique patients across all drugs and therapeutic classes.

TPT derives its data from the Vector One® database which integrates prescription activity from a variety of sources including national retail chains, mass merchandisers, pharmacy benefits

managers and their data systems, physician offices and hospitals. Vector One<sup>®</sup> receives over 1.8 billion prescription claims per year, which represents over 150 million patients tracked across time.

Data for this analysis included patients who were dispensed prescriptions for Trileptal<sup>®</sup> from April 1, 2003 – March 31, 2006 inclusive.

### **IMS HEALTH, NATIONAL DISEASE AND THERAPEUTIC INDEX™ (NDTI™)**

The National Disease and Therapeutic Index™ (NDTI™) is an ongoing survey designed and conducted by IMS Health to provide descriptive information on the patterns and treatment of diseases encountered in office-based practices in the continental U.S. The data are collected from a panel of approximately 3,000 office-based physicians who complete and submit a survey of their practice patterns to IMS Health for two consecutive days per quarter. These data may include profiles and trends of diagnoses, patients, drug products mentioned, and treatment patterns. These data are projected nationally to reflect national prescribing patterns.

NDTI™ uses the term drug uses for mentions of a drug in association with a diagnosis during an office-based patient visit. This term may be duplicated by the number of diagnosis for which the drug is mentioned. It is important to note that a drug use does not necessarily result in prescription being generated. Rather, the term indicates that a given drug was mentioned during an office visit.

For this analysis, we examined annual mentions of Trileptal<sup>®</sup> during office-based physician visits during the time period from April 1, 2003 – March 31, 2006 inclusive.

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<sup>1</sup> IMS Health, National Sales Perspective™, Calendar Years 2003-2005, data extracted March, 2006; original file: 0603oxcr.dvr

<sup>2</sup> French JA, Kanner AM, Bautista J, et al. Efficacy and tolerability of the new antiepileptic drugs I: treatment of new onset epilepsy: report of the Therapeutics and Technology Assessment Subcommittee and Quality Standards Subcommittee of the American Academy of Neurology and the American Epilepsy Society. *Neurology* 2004 62(8):1252-60

<sup>3</sup> French JA, Kanner AM, Bautista J, et al. Efficacy and tolerability of the new antiepileptic drugs II: treatment of refractory epilepsy: report of the Therapeutics and Technology Assessment Subcommittee and Quality Standards Subcommittee of the American Academy of Neurology and the American Epilepsy Society. *Neurology* 2004 62(8):1261-73

<sup>4</sup> National Institute for Clinical Excellence (NICE). New drugs for epilepsy in children. April 2004 URL: <http://www.nice.org.uk/page.aspx?o=113359> Last accessed May 25, 2006

<sup>5</sup> Hirschfeld RM, Kasper S. A review of the evidence for carbamazepine and oxcarbazepine in the treatment of bipolar disorder. *Int J Neuropsychopharmacol* 2004 Dec;7(4):507-22. Epub 2004 Sep 30.

<sup>6</sup> Ghaemi SN, Berv DA, Klugman J, Rosenquist KJ, Hsu DJ. Oxcarbazepine treatment of bipolar disorder. *J Clin Psychiatry* 2003 Aug;64(8):943-5.

<sup>7</sup> Hellewell JS. Oxcarbazepine (Trileptal) in the treatment of bipolar disorders: a review of efficacy and tolerability. *J Affect Disord* 2002 Dec;72 Suppl 1:S23-34.

<sup>8</sup> Evins AE. Efficacy of newer anticonvulsant medications in bipolar spectrum mood disorders. *J Clin Psychiatry* 2003;64 Suppl 8:9-14.

<sup>9</sup> Goodnick PJ. Anticonvulsants in the treatment of bipolar mania. *Expert Opin Pharmacother* 2006 Mar;7(4):401-10.

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Concurrences:

Team Leaders

Laura Governale, Pharm.D. Drug Utilization Data Specialist Team Leader

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