



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

Date: January 31, 2008

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Subject: One-Year Post-Pediatric Exclusivity Post-Marketing Adverse Event
Review, Drug Utilization Analysis
Pediatric Exclusivity Grant Date: November 8, 2006

Drug Name(s): Coreg® (Carvedilol Tablets)

Submission Number: S-016

Application Type/Number: NDA 20-297

Applicant/sponsor: SmithKline Beecham

OSE RCM #: 2007-255

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EXECUTIVE SUMMARY

This review is provided to provide context for the adverse event reporting required by the BPCA and describes the U.S. outpatient drug use patterns for Coreg[®] and generic carvedilol extended release (ER) in the pediatric and adult populations in the years prior to and following the granting of pediatric exclusivity. Proprietary drug use databases licensed by FDA were used to conduct this analysis. This document will refer to the combined total use of Coreg, Coreg Extended Release and generic carvedilol as “carvedilol.”

The Verispan, LLC: Vector One[®]: National database was queried to obtain counts of retail pharmacy carvedilol prescriptions dispensed, as well as stratification of those prescriptions by patient age and prescriber specialty type. The number of carvedilol prescriptions dispensed for all patients increased during each year of the study period. Similar to the overall market data for all age groups, the number of dispensed prescriptions in the pediatric population (ages 0-16 years) has also been increasing annually.

The total number of carvedilol prescriptions dispensed by retail pharmacies increased by 20% from the pre-exclusivity period to the post-exclusivity period. A total of 12.3 million retail carvedilol prescriptions were dispensed during the post-exclusivity 12-month period of December 1, 2006 through November 30, 2007. Most patients (greater than 99%) who received a retail prescription for carvedilol were adults 17 years of age and older. Use in the pediatric population (ages 0-16 years) is concentrated in the 2-11 year old patients who accounted for 55% of the pediatric population that received a carvedilol prescription during the post exclusivity period. Patient-level data were similar to dispensed prescription data.

Most retail prescriptions for carvedilol were written by cardiologists who accounted for approximately 35% of carvedilol dispensing during the pre- and post-exclusivity years. Internal medicine was the second most common prescriber with approximately 25% of dispensing in each year.

Among adults, the most common indications for use were congestive heart failure (ICD-9 428.0) and hypertension (ICD-9 401.9) which accounted for 25% and 27% of carvedilol physician mentions during the post-exclusivity period. The use among pediatric patients was too low to evaluate.

1 BACKGROUND

1.1 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 in children 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 soon after the one-year anniversary of granting exclusivity. This review is in addition to the routine post-marketing safety surveillance activities the FDA performs for all marketed drugs.

1.2 REGULATORY HISTORY

Coreg[®] (carvedilol) is a nonselective β -adrenergic blocking agent with α 1 blocking activity formulated as an immediate (Coreg) and extended release (Coreg CR) tablets for oral administration.

Coreg[®] was approved for marketing on September 14, 1995, under NDA 20-297. The product is currently labeled for the treatment of mild-to-severe chronic heart failure of ischemic or cardiomyopathic origin, to reduce cardiovascular mortality in clinically stable patients who have survived the acute phase of a myocardial infarction and have a left ventricular ejection fraction of ≤ 40 (with or without symptomatic heart failure), for the management of essential hypertension, for the treatment of hypertension (either alone or in combination), and for the long term treatment of angina pectoris. There are no approved pediatric indications.

In response to a FDA Pediatric Written Request for studies of Coreg[®] in pediatric patients, the sponsor conducted a multi-center, 8 month, placebo controlled study in children with congestive heart failure evaluating the effect of twice daily administration of carvedilol and an open-label extension study to evaluate twice daily carvedilol in pediatric patients with chronic heart failure. These studies concluded that the use of carvedilol in doses up to 25 mg BID was not efficacious in children with heart failure. There were no unexpected safety events. Pediatric Exclusivity was granted on November 8, 2006.

2 METHODS AND MATERIALS

2.1 INTRODUCTION

Using the currently available data resources, this review describes the outpatient drug use patterns for carvedilol in the pediatric and adult populations in the years prior to and following the granting of pediatric exclusivity for November 8, 2006. Proprietary drug use databases licensed by FDA were used to conduct this analysis.

2.2 DETERMINING SETTING OF CARE

IMS Health, IMS National Sales Perspectives[™] data were used to determine the primary settings in which carvedilol (Coreg[®] and generic carvedilol) is sold. Cumulative sales of these products by number of oral dosage forms (i.e., “extended units” or EUs) sold from the manufacturer into the various retail and non-retail channels of distribution were analyzed for three 12-month periods from December 1, 2004 through November 30, 2007. A complete description of this IMS Health database is provided in Appendix One.

Using IMS Health, IMS National Sales Perspectives[™] data, we determined that sales distribution to retail pharmacies accounted for roughly 68%, and outpatient mail order pharmacies accounted for roughly 18% of the total amount of carvedilol tablets sold during the three 12-month study periods from December 1, 2004 through November 30, 2007. The remaining 14% of annual sales were to non-retail distribution channels which include hospitals, clinics, HMOs, educational facilities and prisons.

Because most carvedilol sold during this time period went to retail and mail order pharmacies, we examined utilization patterns focusing on the outpatient setting. Sales data indicate that the Verispan database VONA is the most appropriate data source to measure the use of these products among the databases licensed by FDA.

2.3 DATA SOURCES USED

Outpatient use and patient demographics were measured with two data sources from Verispan, LLC: Vector One[®]: National (VONA), and Total Patient Tracker (TPT). From these sources, nationally projected estimates of the number of prescriptions dispensed by retail pharmacies and the number of patients who received a prescription dispensed by retail pharmacies for carvedilol were obtained. Indications for use were obtained from the Verispan, Physician Drug and Diagnosis Audit (PDDA). Outpatient drug utilization patterns were examined for three 12-month

periods from December 1, 2004 through November 30, 2007. Complete descriptions of the databases used are provided in Appendix One.

2.4 PRODUCTS INCLUDED

In addition to examining drug utilization patterns for carvedilol, we examined outpatient utilization patterns for other selected beta-blockers. These products were selected based on their indication and dosage form. Comparator products in the carvedilol market include metoprolol (Toprol[®] XL, Metoprolol XL), bisoprolol fumarate (Zebeta[®]), and propranolol (Innopran[®] XL, propranolol LA).

3 RESULTS

3.1 DISPENSED PRESCRIPTIONS FOR THE CARVEDILOL MARKET

The total number of prescriptions dispensed by retail pharmacies for all products within the carvedilol market¹ was obtained using Verispan, Vector One[®]: National (Appendix 1, Table 1). The overall number of prescriptions dispensed for this defined market of products has been increasing annually for each of the three 12-month periods examined with a growth of 9% from the pre- to post-exclusivity years (December 2005 – November 2006 through December 2006 – November 2007). The most commonly dispensed products during the post-exclusivity year (December 2006 through November 2007) were the extended release metoprolol products (Toprol XL and Metoprolol XL) which accounted for 77% of the market during the pre-exclusivity year and 75% of the market during the post-exclusivity year. Carvedilol was the second most commonly dispensed product within the defined market with the number of prescriptions dispensed increasing by 20% from 10.3 million prescriptions (21% of the market) during the pre-exclusivity year and 12.4 million prescriptions (23% of the market) during the post-exclusivity year. Over the three 12-month periods examined, the number of prescriptions dispensed for carvedilol increased by 54%. During the post-exclusivity year (December 2006 – November 2007), generic carvedilol and Coreg CR became available and together accounted for 25% of all carvedilol prescriptions dispensed.

An examination of the carvedilol market by age resulted in similar findings to the overall market. For each year of this analysis, metoprolol was the most commonly dispensed product to patients 0-16 years of age while carvedilol accounted for 37% of the pediatric market during the pre-exclusivity year and 38% of the pediatric market during the post-exclusivity year.

3.2 DISPENSED PRESCRIPTIONS FOR CARVEDILOL

The total number of carvedilol prescriptions dispensed by retail pharmacies increased by 20% from the pre-exclusivity period (December 2005 – November 2006) to the post-exclusivity period (December 2006 – November 2007) (Appendix 1, Table 3). A total of 10.3 million retail carvedilol prescriptions were dispensed during the pre-exclusivity 12-month period of December 1, 2005 through November 30, 2006. A total of 12.4 million retail carvedilol prescriptions were dispensed during the post-exclusivity 12-month period of December 1, 2006 through November 30, 2007.

¹ Market defined as: Toprol XL, Metoprolol XL, Coreg, Carvedilol, Coreg CR, Bisoprolol Fumarate, Zebeta, Innopran XL, Propranolol LA

3.3 PATIENT DEMOGRAPHICS

3.3.1 PRESCRIPTIONS DISPENSED

Verispan, LLC: Vector One[®], Prescription Services database was queried to obtain counts of carvedilol retail pharmacy prescriptions dispensed, stratified by patient age.

Most prescriptions (greater than 99.5%) were dispensed to adults over 16 years of age (Appendix 1, Table 3). A total of 12,720 retail carvedilol prescriptions were dispensed to children from 0 to 16 years of age during the pre-exclusivity 12-month period of December 1, 2005 through November 30, 2006. A total of 13,848 retail carvedilol prescriptions were dispensed to children from 0 to 16 years of age during the post-exclusivity 12-month period of December 1, 2006 through November 30, 2007. This represented an increase of 9% between pre- and post-exclusivity time periods for the overall pediatric population.

Examination of the pediatric age subgroups showed that carvedilol is most commonly dispensed to patients 2 to 11 years of age. This age band accounted for 55% of pediatric dispensing during the pre-exclusivity year (7,022 prescriptions) and 57% of pediatric dispensing during the post exclusivity year (7,950 prescriptions), a relative increase of 13%. There was a roughly 2% decline in the number of prescriptions dispensed to patients 0-1 years of age from 1,306 prescriptions in the pre-exclusivity year (10% of pediatric prescriptions) to 1,085 prescriptions in the post-exclusivity year (8% of pediatric prescriptions). The proportion of dispensing for patients 12-16 years of age remained stable at 35% with 4,392 prescriptions in the pre-exclusivity year and 4,813 prescriptions in the post-exclusivity year.

3.3.2 PATIENT COUNTS FOR DISPENSED PRESCRIPTIONS

Verispan, LLC: Total Patient Tracker (TPT) was queried to obtain counts of patients who received at least one retail pharmacy prescription for carvedilol.

There were 2 million patients who received an outpatient prescription through retail pharmacies during the pre-exclusivity 12-month period of December 1, 2005 through November 30, 2006, and 2.3 million during the post-exclusivity 12-month period of December 1, 2006 through November 30, 2007; an increase of 14%. Most patients (i.e., 99%) who received carvedilol via retail pharmacy prescriptions were adults 17 years of age and older. Analysis of patient-level data in the pediatric population revealed similar trends which were similar to those seen in the dispensed prescription data. Pediatric patients 2-11 years of age accounted for the largest proportion of the carvedilol pediatric patients, increasing from 1,679 in the pre-exclusivity year (53%) to 1,667 during the post-exclusivity year (55%).

3.4 PRESCRIBER SPECIALTY

Verispan, LLC: Vector One[®]: National database was queried to obtain counts of retail pharmacy carvedilol prescriptions dispensed, stratified by prescriber specialty (Appendix 1, Table 5).

Most retail prescriptions for carvedilol were written by cardiologists who accounted for approximately 35% of carvedilol dispensing during the pre- and post-exclusivity years. Internal medicine was the second most common prescriber with approximately 25% of dispensing in each year. Pediatricians accounted for less than 1% of carvedilol prescriptions and were the 9th most common prescriber during the pre-exclusivity 12-month period of December 1, 2005 through November 30, 2006 and the post-exclusivity 12-month period of December 1, 2006 through November 30, 2007.

3.5 INDICATION FOR USE

Verispan, LLC: Physician Drug and Diagnosis Audit (PDDA) survey was queried to obtain counts of office-based physician visits for carvedilol, stratified by 4-digit diagnosis codes associated with the visits (Appendix 1, Table 6).

Adults aged 17 years and older accounted for the nearly all carvedilol associated office-based physician visits during the three 12-month study periods examined. Among adults, the most common indications for use were congestive heart failure (ICD-9 428.0) and hypertension (ICD-9 401.9) which accounted for 25% and 27% of carvedilol physician mentions during the post-exclusivity period. The use among pediatric patients was too low to evaluate.

4 DISCUSSION

4.1 DATA CAVEATS AND LIMITATIONS

Findings from this review should be interpreted in the context of the known limitations of the databases used. We estimated that the use of carvedilol was primarily in the outpatient settings based on the IMS Health, IMS National Sales Perspectives™. These data do not provide a direct estimate of use but do provide a national estimate of the number of tablets 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 the facilities purchase drugs in quantities reflective of actual patient use. The actual proportion of overall prescription dispensing by each pharmacy channel will differ based on the average prescription size dispensed.

The Verispan Physician Drug and Diagnosis Audit (PDDA) 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, as in the case of carvedilol. Verispan recommends trending PDDA data only when projected counts exceed 100,000 uses or visits per year.

While we conducted a comprehensive analysis of the use of this product in the outpatient settings in which the majority of use occurred, use outside of the retail pharmacy setting was not captured in our analysis.

5 CONCLUSIONS

Based on the databases licensed by FDA, a very small proportion of the total number of patients treated with carvedilol are pediatric patients (less than 0.5% of the total number patients who received carvedilol from a retail pharmacy during the study period). Use in the overall pediatric population is concentrated in the 2-11 year old patients which accounted for 55% of the pediatric population that received a carvedilol prescription during the post exclusivity period.

APPENDICES

APPENDIX ONE: Data Tables

Table 1. Projected Number of Retail Prescriptions Dispensed (in Thousands) through U.S. Retail Outpatient Pharmacies for the Carvedilol Market, December 1, 2004 - November 30, 2007

	December 2004 - November 2005		December 2005 - November 2006		December 2006 - November 2007	
	Rxs (000)	(%)	Rxs (000)	(%)	Rxs (000)	(%)
TOTAL MARKET	42,524	(100)	48,808	(100)	53,283	(100)
Metoprolol	33,419	(78.6)	37,323	(76.5)	39,670	(74.5)
Carvedilol	8,041	(18.9)	10,347	(21.2)	12,370	(23.2)
Coreg	8,041	(100)	10,347	(100)	9,252	(74.8)
Carvedilol	--	--	--	--	2,063	(16.7)
Coreg CR	--	--	--	--	1,055	(8.5)
Bisoprolol	807	(1.9)	884	(1.8)	967	(1.8)
Propranolol	258	(0.6)	254	(0.5)	277	(0.5)

Source: Verispan Vector One: National Data Extracted 9-2007 file: 2007-255 VONA Carvedilol Market
Market defined as: Toprol XL, Metoprolol XL, Coreg, Carvedilol, Coreg CR, Bisoprolol Fumarate, Zebeta, Innopran XL, Propranolol LA

Table 2. Projected Number of Pediatric (ages 0-16 years) Retail Prescriptions Dispensed (in Thousands) through U.S. Retail Outpatient Pharmacies for the Carvedilol Market, December 1, 2004 – November 30, 2007

	December 2004 - November 2005		December 2005 - November 2006		December 2006 - November 2007	
	Rxs (000)	(%)	Rxs (000)	(%)	Rxs (000)	(%)
Total Market	42,524	(100)	48,808	(100)	53,283	(100)
0-16	41	(0.1)	35	(0.1)	37	(0.1)
Metoprolol	26	(63.4)	21	(60)	21	(56.8)
Carvedilol	12	(29.3)	13	(37.1)	14	(37.8)
Coreg	12	(100)	13	(100)	11	(78.6)
Carvedilol	--	--	--	--	2	(14.3)
Coreg CR	--	--	--	--	1	(7.1)
Propranolol HCl	1	(2.4)	1	(2.9)	1	(2.7)
Bisoprolol fumarate	1	(2.4)	1	(2.9)	1	(2.7)
17+	42,241	(99.3)	48,637	(99.6)	53,137	(99.7)
Unspecified Age	242	(0.6)	136	(0.3)	109	(0.2)

Source: Verispan Vector One: National Data Extracted 9-2007 file: 2007-255 VONA Carvedilol Age-Market
Market defined as: Toprol XL, CarvedilolXL, Coreg, Carvedilol, Coreg CR, Bisoprolol Fumarate, Zebeta, Innopran XL, Propranolol LA

Table 3. Projected Number of Pediatric (ages 0-16 years) Retail Prescriptions Dispensed through U.S. Retail Outpatient Pharmacies for the Carvedilol Products December 1, 2004 – November 30, 2007, (Stratified by Patient Age in Years)

	December 2004 - November 2005		December 2005 - November 2006		December 2006 - November 2007	
	Rxs	(%)	Rxs	(%)	Rxs	(%)
Carvedilol	8,040,525	(100)	10,346,604	(100)	12,369,626	(100)
0-16	12,380	(0.2)	12,720	(0.1)	13,848	(0.1)
0-1	1,389	(11.2)	1,306	(10.3)	1,085	(7.8)
2-11	7,450	(60.2)	7,022	(55.2)	7,950	(57.4)
12-16	3,541	(28.6)	4,392	(34.5)	4,813	(34.8)
17+	7,944,967	(98.8)	10,291,526	(99.5)	12,324,139	(99.6)
UNSPEC.	83,178	(1)	42,358	(0.4)	31,639	(0.3)

Source: Verispan Vector One: National Data Extracted 9-2007 file: 2007-255 VONA Carvedilol by age
Carvedilol products includes Coreg, Coreg CR, carvedilol generic

Table 4. Projected Number of Patients Receiving a Carvedilol Prescription through U.S. Retail Outpatient Pharmacies by Patient Age, December 1, 2004 - November 30, 2007 (Stratified by Patient Age in Years)

	December 1, 2004- November 30, 2005		December 1, 2005- November 30, 2006		December 1, 2006- November 30, 2007	
	Projected Patients	(%)	Projected Patients	(%)	Projected Patients	(%)
Carvedilol	1,613,975	100%	2,013,826	100%	2,297,244	100%
0 - 16	3,097	0.2%	3,170	0.2%	3,015	0.1%
0 - 1	499	16.1%	501	15.8%	387	12.8%
2 - 11	1,848	59.7%	1,679	53.0%	1,667	55.3%
12 - 16	871	28.1%	1,104	34.8%	1,074	35.6%
17+	1,581,684	98.0%	1,988,147	98.7%	2,276,285	99.1%
Unknown	92,096	5.7%	88,793	4.4%	91,923	4.0%

Source: Verispan Vector One: Total Patient Tracker Data Extracted 1/2008 Source Files: 2007-255 TPT Carvedilol 0-16.xls, 2007-255 TPT Carvedilol.xls

*Values may not sum exactly due to patient aging during study period

Table 5. Projected Number of Pediatric (ages 0-16 years) Prescriptions Dispensed through U.S. Retail Outpatient Pharmacies for the Carvedilol Products December 1, 2004 – November 30, 2007, (Stratified by Physician Specialty)

	December 2004 - November 2005		December 2005 - November 2006		December 2006 - November 2007	
	Rxs (000)	(%)	Rxs (000)	(%)	Rxs (000)	(%)
Carvedilol	8,041	(100)	10,347	(100)	12,370	(100)
Cardiology	2,895	(36)	3,698	(35.7)	4,324	(35)
Internal med	1,882	(23.4)	2,596	(25.1)	3,147	(25.4)
Gp/Fm/Do	1,435	(17.8)	2,101	(20.3)	2,672	(21.6)
Unspecified	914	(11.4)	670	(6.5)	657	(5.3)
Nurse pract	131	(1.6)	209	(2)	282	(2.3)
Hospitalists	151	(1.9)	198	(1.9)	208	(1.7)
Nephrology	111	(1.4)	160	(1.5)	203	(1.6)
Physician Assis	60	(0.7)	98	(0.9)	138	(1.1)
Pediatrics	52	(0.6)	79	(0.8)	100	(0.8)
Endocrinology	54	(0.7)	74	(0.7)	88	(0.7)
All Others	355	(4.4)	464	(4.5)	551	(4.5)

Source: Verispan Vector One: National Data Extracted 9-2007 file: 2007-255 VONA Carvedilol by age
Carvedilol products includes Coreg, Coreg CR, carvedilol generic

Table 6. Diagnoses Associated with a Mention of Carvedilol During Office Based Physician Visits (in thousands), December 2004 - November 2007, (Stratified by Patient Age and Diagnosis Code)

	December 2004 - November 2005		December 2005 - November 2006		December 2006 - November 2007	
	Uses (000)	(%)	Uses	Share	Uses	Share
Carvedilol	7,471	(100)	8,257	(100)	7,499	(100)
12-16	--	--	8	(0.1)	--	--
4280 Congestive Heart Failure	--	--	8	(100)	--	--
17+	7,267	(97.3)	7,920	(95.9)	7,212	(96.2)
4280 Congestive Heart Failure	2,192	(30.2)	2,019	(25.5)	1,824	(25.3)
4019 Hypertension Nos	1,388	(19.1)	1,291	(16.3)	1,923	(26.7)
4140 Coronary Atherosclerosis	771	(10.6)	1,223	(15.4)	703	(9.7)
4254 Prim Cardiomyopathy Nec	766	(10.5)	745	(9.4)	689	(9.6)
4029 Hypertensive Hrt Dis Nos	462	(6.4)	602	(7.6)	127	(1.8)
All Others	1,688	(23.2)	2,041	(25.8)	1,947	(27)
UNSPEC.	204	(2.7)	329	(4)	287	(3.8)

Source: Verispan Physician Drug and Diagnosis Audit, Data Extracted 9-2007 File: 2007-255 PDDA Carvedilol Diags

APPENDIX TWO: Database Descriptions

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, mail order pharmacies, pharmacy benefits managers and their data systems, and provider groups. Vector One receives over 2 billion prescription claims, representing over 160 million unique patients.

Prescriptions are captured from a sample of approximately 54,000 pharmacies throughout the US. The pharmacies in the data base account for nearly all retail pharmacies and represent approximately 50% of 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.

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 in the retail outpatient setting.

TPT derives its data from the Vector One database which integrates prescription activity from a variety of sources including national retail chains, mail order pharmacies*, mass merchandisers, pharmacy benefits managers and their data systems. Vector one receives over 2 billion prescription claims per year, which represents over 160 million patients tracked across time.

Verispan, LLC: Physician Drug & Diagnosis Audit® (PDDA)

Verispan's Physician Drug & Diagnosis Audit (PDDA) is a monthly survey designed to provide descriptive information on the patterns and treatment of diseases encountered in office-based physician practices in the U.S. The survey consists of data collected from approximately 3,100 office-based physicians representing 29 specialties across the United States that report on all patient activity during one typical workday per month. These data may include profiles and trends of diagnoses, patients, drug products mentioned during the office visit and treatment patterns. The data are then projected nationally by physician specialty and region to reflect national prescribing patterns.

Verispan uses the term "drug uses" to refer to 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.

IMS Health, IMS National Sales Perspectives™, Retail and Non-Retail

The IMS Health, IMS National Sales Perspective™ 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. 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. The IMS Health, IMS National Sales Perspectives™ measures the volume of drug products moving from manufacturer into retail and non-retail settings in terms of sales dollars, eaches, extended units, and share of market. These data are based on national projections.

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