Modular Program Report

The following report(s) provides findings from an FDA-initiated query using its Mini-Sentinel pilot. While Mini-Sentinel queries may be undertaken to assess potential medical product safety risks, they may also be initiated for various other reasons. Some examples include determining a rate or count of an identified health outcome of interest, examining medical product use, exploring the feasibility of future, more detailed analyses within Mini-Sentinel, and seeking to better understand the capabilities of the Mini-Sentinel pilot.

Data obtained through Mini-Sentinel are intended to complement other types of evidence such as preclinical studies, clinical trials, postmarket studies, and adverse event reports, all of which are used by FDA to inform regulatory decisions regarding medical product safety. The information contained in this report is provided as part of FDA's commitment to place knowledge acquired from the Mini-Sentinel pilot in the public domain as soon as possible. Any public health actions taken by FDA regarding products involved in Mini-Sentinel queries will continue to be communicated through existing channels.

FDA wants to emphasize that the fact that FDA has initiated a query involving a medical product and is reporting findings related to that query does not mean that FDA is suggesting health care practitioners should change their prescribing practices for the medical product or that patients taking the medical product should stop using it. Patients who have questions about the use of an identified medical product should contact their health care practitioners.

The following report contains a description of the request, request specifications, and results from the modular program run(s).

If you are using a web page screen reader and are unable to access this document, please contact the Mini-Sentinel Operations Center for assistance at info@mini-sentinel.org.

Overview

Request Description

These results were generated using 2 runs of the Mini-Sentinel Modular Program #3 Version 1.2. The query was run against the Mini-Sentinel Distributed Database and distributed on October 28, 2011. Counts of users, dispensings, and total days supplied were generated for duloxetine, pregabalin, and milnacipran separately and all three combined as one drug class among those previously diagnosed with myalgia and myositis (ICD-9-CM diagnosis 729.1).

The lookback period for a pre-existing condition of myalgia and myositis was set to 90 days. The maximum allowable treatment gap was set to 14 days. The minimum episode duration, and minimum episode days supplied were set to zero. The drug washout period was set to zero to estimate prevalent use. The program data range was January 1, 2006 to December 31, 2010 and the care setting was restricted to ambulatory care visits only. The output was stratified by age group (0-17, 18-64, and 65+ years), sex, and year.

Please review the Notes below and the Specification page for request details.

Request ID

MPR19

Specifications

Program parameter inputs and scenarios

Table 1

Table of the summary of drug use for duloxetine, milnacipran, and pregabalin in the MSDD between January 1, 2006 and December 31, 2010 by age group, sex, index year, and in aggregate.

Figures 1-4

Four graphs of aggregate prevalent counts of users, dispensings, total days supplied, days per user, dispensings per user, and days per dispensing by drug class/product.

Notes:

The program was run for the entire query period (January 1, 2006 - December 31, 2010). When examining the yearly stratification in the incident output from Modular Program 3, note once an incident user is first encountered, this user will not be counted for subsequent years. Consequently, this situation applies to the estimation of prevalent use in the above program. The user will only be counted once for the entire time period even if the drug use occurred in multiple years.

Please contact the Mini-Sentinel Operations Center (MSOC_Requests@harvardpilgrim.org) for questions and to provide comments/suggestions for future enhancements to this document.

Modular Program Specifications

Modular Program #3 was used to investigate the use of duloxetine, milnacipran, and pregabalin separately and all three combined as one drug class among those previously diagnosed with myalgia and myositis (ICD-9 729.1). The program was run twice for the entire time period of January 1, 2006 to December 31, 2010 and the care setting was restricted to ambulatory care visits only. The maximum allowable treatment gap was set to 14 days, and age groups examined were 0-17, 18-64, and 65+ years. The lookup period for myalgia and myositis was set to 90 days. The minimum episode duration, and minimum episode days supplied were set to zero. The drug washout period was set to zero to estimate prevalent use. In total, there were 4 scenarios that differed by incident exposure.

	Drug/Exposure Criteria					Pre-Existing Condition Criteria				
Scenario	Incident Exposure	Washout (days)	Min Episode Duration (days)	Min Days Supplied	Episode Gap (days)	Pre-Existing Condition	Care Setting	Principal Dx?	Lookback Type*	Lookback Period (days)
1	Duloxetine	0	0	0	14	Myalgia	AV	No	Fixed	90
2	Milnacipran	0	0	0	14	Myalgia	AV	No	Fixed	90
3	Pregabalin	0	0	0	14	Myalgia	AV	No	Fixed	90
4	Any Drug**	0	0	0	14	Myalgia	AV	No	Fixed	90

*A "Fixed" lookback type for the pre-existing condition will look for the pre-existing condition during a specified number of days (lookback period) prior to the index date.

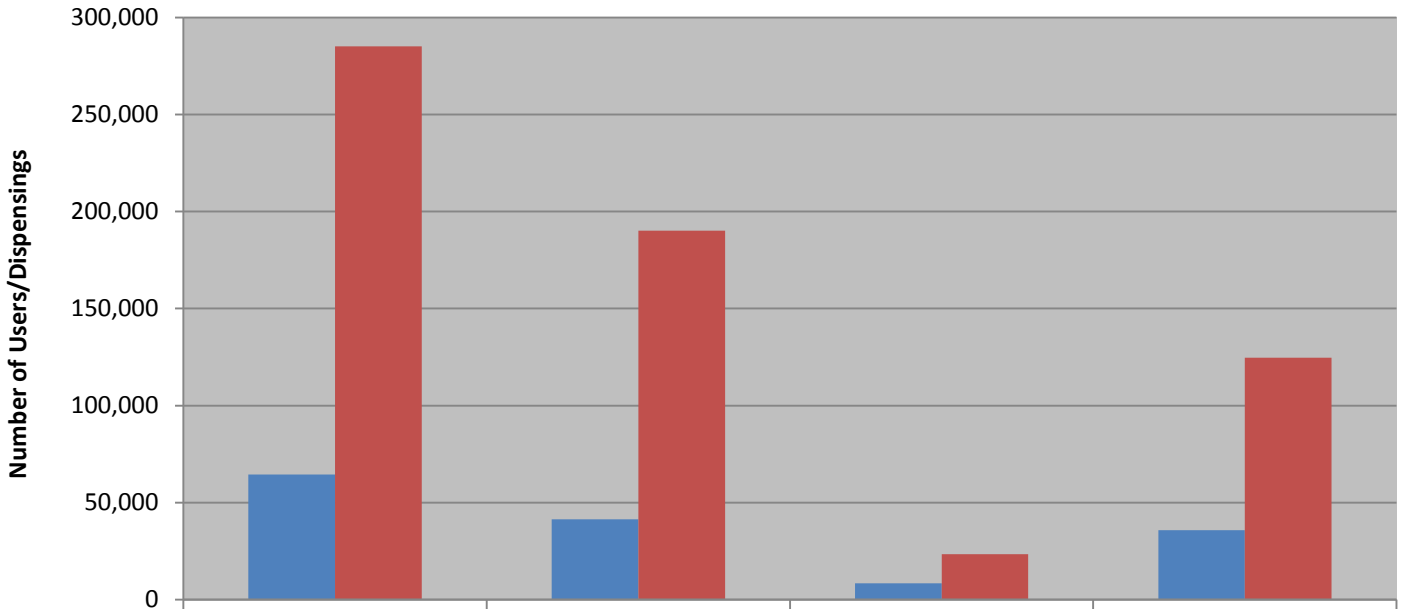
**The "Any Drug" group defines incident exposure as exposure to any of the following drugs: Duloxetine, Milnacipran, or Pregabalin.

Table 1. Summary of Drug Use for Duloxetine, Milnacipran, and Pregabalin in the MSDD between January 1, 2006 and December 31, 2010

		Each Drug Individually		
	Any Drug*	Duloxetine	Milnacipran	Pregabalin
Overall				
Users	***64,414***	***41,343***	***8,353***	***35,724***
Dispensings	***285,174***	***190,122***	***23,377***	***124,657***
Total Days Supplied	***9,432,253***	***6,505,237***	***726,805***	***3,892,333***
Age Group				
0 to 17 years				
Users	352	234	11	175
Dispensings	1,311	845	16	573
Total Days Supplied	40,036	25,089	373	17,994
18 to 64 years				
Users	56,519	36,637	7,549	31,189
Dispensings	254,989	170,297	21,233	110,437
Total Days Supplied	8,366,321	5,787,305	653,228	3,414,119
65+ years				
Users	7,543	4,472	793	4,360
Dispensings	28,874	18,980	2,128	13,647
Total Days Supplied	1,025,896	692,843	73,204	460,220
Sex				
Female				
Users	55,625	35,971	7,671	30,881
Dispensings	248,871	167,522	21,661	107,460
Total Days Supplied	8,265,605	5,761,950	673,766	3,356,429
Male				
Users	8,717	5,325	663	4,806
Dispensings	36,038	22,373	1,668	17,098
Total Days Supplied	1,158,323	735,936	51,527	533,302
Unknown				
Users	72	47	19	37
Dispensings	265	227	48	99
Total Days Supplied	8,325	7,351	1,512	2,602
Index Year				
2006				
Users	11,093	8,394	0	3,791
Dispensings	67,887	50,668	0	15,080
Total Days Supplied	2,270,277	1,752,124	0	457,120
2007				
Users	11,203	6,653	0	7,181
Dispensings	54,642	33,581	0	27,095
Total Days Supplied	1,851,885	1,185,855	0	848,747
2008				
Users	16,358	8,630	0	12,961
Dispensings	70,791	39,961	0	46,732
Total Days Supplied	2,308,525	1,351,832	0	1,465,890
2009				
Users	13,471	9,786	3,036	6,575
Dispensings	55,533	42,063	9,741	21,901
Total Days Supplied	1,806,604	1,411,531	291,490	681,907
2010				
Users	12,289	7,880	5,317	5,216
Dispensings	36,321	23,849	13,636	13,849
Total Days Supplied	1,194,962	803,895	435,315	438,669

*The "Any Drug" group defines incident exposure as exposure to any of the following drugs: Duloxetine, Milnacipran, or Pregabalin.

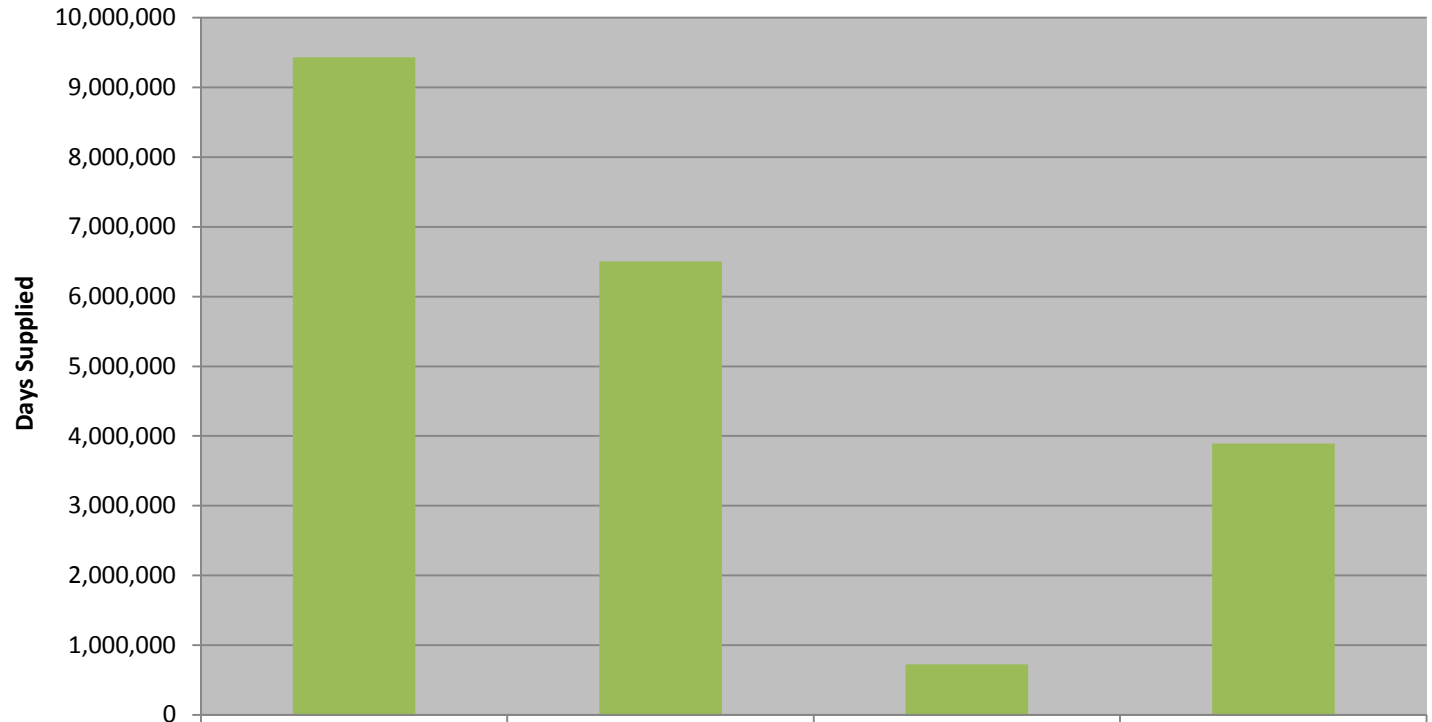
Figure 1. Summary of Users and Dispensings in the MSDD between January 1, 2006 and December 31, 2010 by Drug Class/Product



	ANY DRUG*	DULOXETINE	MILNACIPRAN	PREGABALIN
Users	64,414	41,343	8,353	35,724
Dispensings	285,174	190,122	23,377	124,657

*The "Any Drug" group defines incident exposure as exposure to any of the following drugs: Duloxetine, Milnacipran, or Pregabalin.

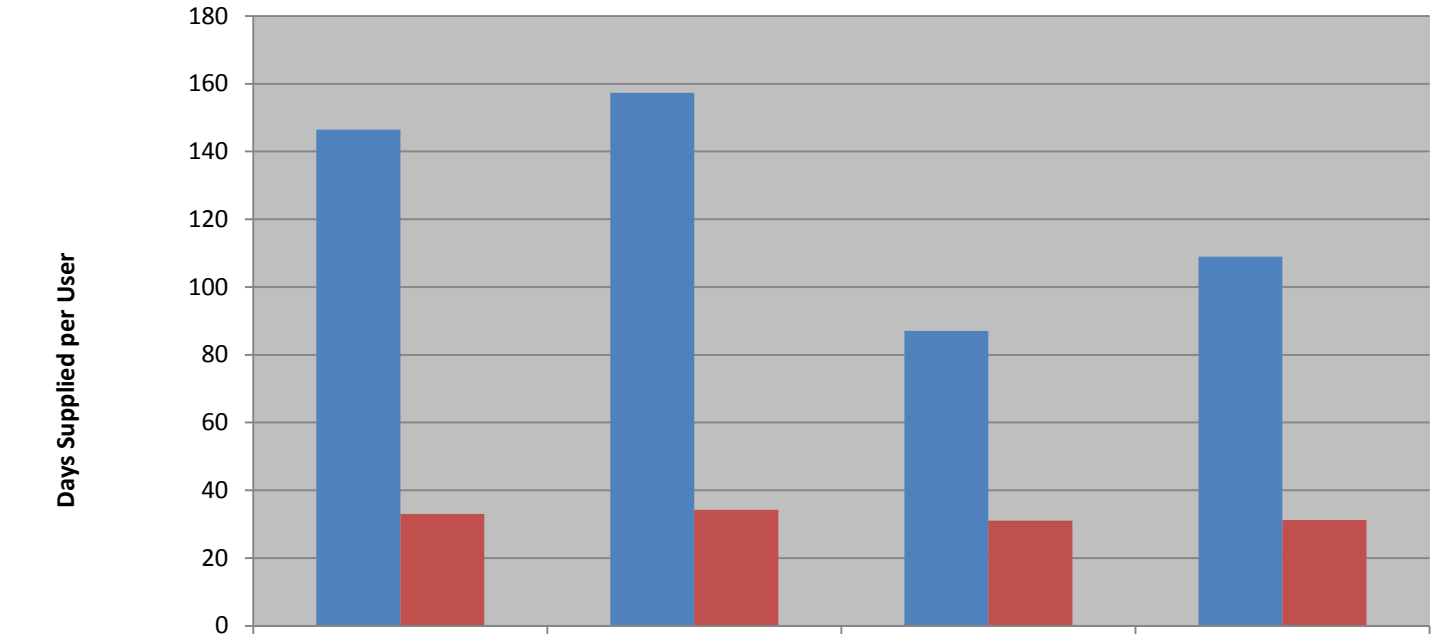
Figure 2. Summary of Days Supplied in the MSDD between January 1, 2006 and December 31, 2010 by Drug Class/Product



	ANY DRUG*	DULOXETINE	MILNACIPRAN	PREGABALIN
TotalDaysSupp	9,432,253	6,505,237	726,805	3,892,333

*The "Any Drug" group defines incident exposure as exposure to any of the following drugs: Duloxetine, Milnacipran, or Pregabalin.

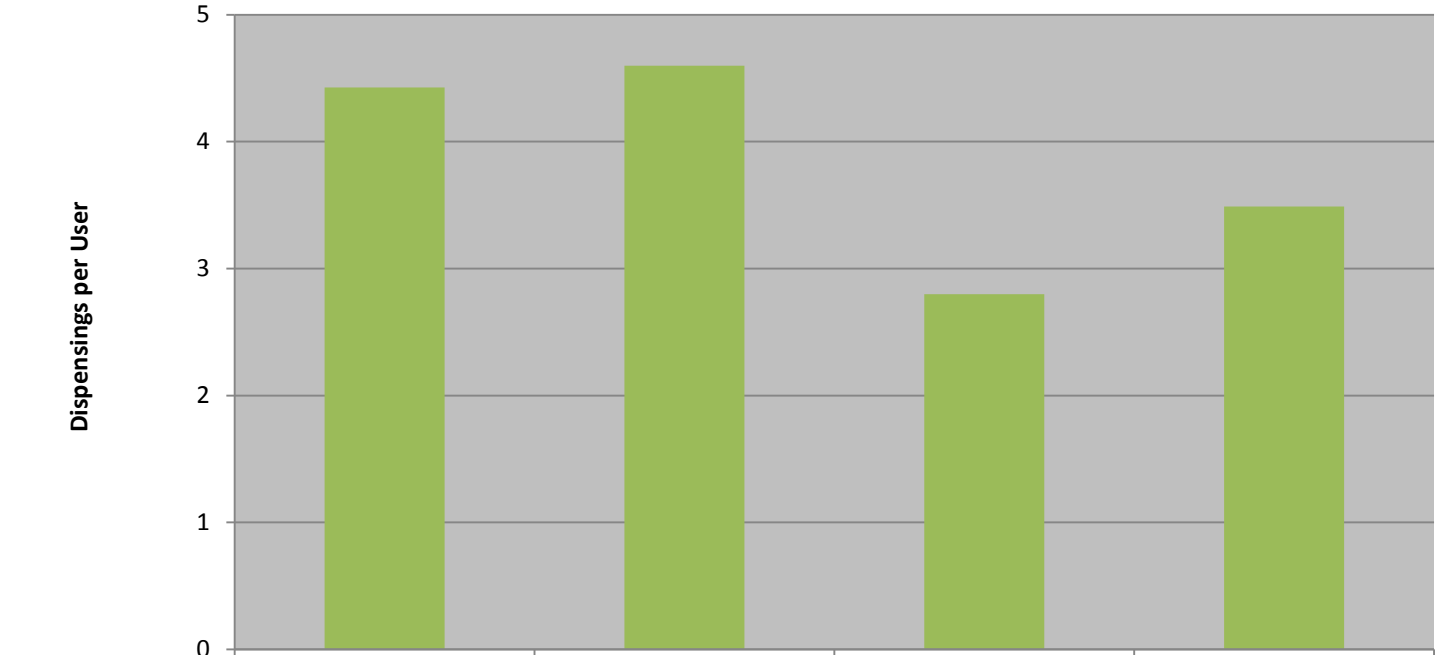
Figure 3. Summary of Days Supplied per User and Days per Dispensing in the MSDD between January 1, 2006 and December 31, 2010 by Drug Class/Product



	ANY DRUG*	DULOXETINE	MILNACIPRAN	PREGABALIN
Days Supplied/User	146.43	157.35	87.01	108.96
Days/Dispensing	33.08	34.22	31.09	31.22

*The "Any Drug" group defines incident exposure as exposure to any of the following drugs: Duloxetine, Milnacipran, or Pregabalin.

Figure 4. Summary of Dispensings per User in the MSDD between January 1, 2006 and December 31, 2010 by Drug Class/Product



	ANY DRUG*	DULOXETINE	MILNACIPRAN	PREGABALIN
Dispensings/User	4.43	4.60	2.80	3.49

*The "Any Drug" group defines incident exposure as exposure to any of the following drugs: Duloxetine, Milnacipran, or Pregabalin.