



## ***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).

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## Overview

<b><u>Request Description</u></b>	<p>These results were generated using one run of the Mini-Sentinel Modular Program #1 (Version 1.0). The query was run against the <b>Mini-Sentinel Distributed Database</b> and distributed on <b>August 9, 2011</b>. This request generated counts of users of Lindane, a second line agent for the treatment of lice/scabies.</p> <p>Results presented in this report provide counts of prevalent and incident users, dispensings, and days supplied of Lindane. Incident Lindane use was established using a drug washout period of 183 days. The program was run from January 1, 2000 to May 31, 2011.</p> <p>Please review the Notes below and refer to the specifications page for request details.</p>
<b><u>Request ID</u></b>	MSY2_MPR11
<b><u>Specifications</u></b>	Program parameter inputs and scenario
<b><u>Table 1</u></b>	Table of aggregate counts of prevalent Lindane users, days supplied, and dispensings, as well as the number of days supplied per user, dispensings per user, and days supplied per dispensing by age group, sex, and year.
<b><u>Table 2</u></b>	Table of aggregate counts of incident Lindane users, days supplied, and dispensings, as well as the number of days supplied per user, dispensings per user, and days supplied per dispensing by age group, sex, and year.
<b><u>Figure 1</u></b>	Figure of the number of prevalent and incident Lindane dispensings by month (January 2000- May 2011)
<b><u>Notes:</u></b>	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 #1 was used to investigate the number of prevalent and incident users of lindane. The query period was from January 1, 2000 to May 31, 2011. This request examined 10 age groups, split as follows: 0-1, 2-4, 5-9, 10-14, 15-18, 19-21, 22-44, 45-64, 65-74, 75+ years. A total one scenario was examined in this report with a washout period of 183 days. See below for a description of this scenario.

<b>Drug/Exposure Criteria</b>			
<b>Scenario</b>	<b>Incident exposure</b>	<b>Incident w/ respect to (incidence criteria):</b>	<b>Washout (days)</b>
<b>1</b>	Lindane	Lindane	183

**Table 1. Number of Prevalent Lindane Users, Dispensings, and Total Days Supplied, Dispensings per User, Days per Dispensing and Days per User by Age Group and Sex and Year (2000-2010)**

		Users	Dispensings	Days Supplied	Dispensings per User	Days Supplied per Dispensing	Days Supplied per User
<b>Overall</b>		<b>140,073</b>	<b>224,222</b>	<b>1,475,262</b>	<b>1.60</b>	<b>6.58</b>	<b>10.53</b>
Age group	0 to 1 years	1,388	2,441	13,232	1.76	5.42	9.53
	2 to 4 years	10,661	19,850	112,067	1.86	5.65	10.51
	5 to 9 years	25,869	46,928	282,967	1.81	6.03	10.94
	10 to 14 years	20,881	35,195	212,901	1.69	6.05	10.20
	15 to 18 years	9,807	14,055	89,258	1.43	6.35	9.10
	19 to 21 years	5,710	7,887	56,973	1.38	7.22	9.98
	22 to 44 years	36,206	55,146	373,200	1.52	6.77	10.31
	45 to 64 years	20,397	30,497	232,434	1.50	7.62	11.40
	65 to 74 years	4,411	6,050	50,980	1.37	8.43	11.56
75+ years	4,743	6,173	51,250	1.30	8.30	10.81	
Sex	Female	94,854	158,123	1,027,119	1.67	6.50	10.83
	Male	45,074	65,901	446,896	1.46	6.78	9.91
	Unknown	145	198	1,247	1.37	6.50	8.60
Year	2000	38,579	51,507	375,940	1.34	7.30	9.74
	2001	30,018	40,261	294,206	1.34	7.31	9.80
	2002	19,790	27,364	149,619	1.38	5.47	7.56
	2003	15,854	22,172	115,494	1.40	5.21	7.28
	2004	16,921	23,091	114,726	1.36	4.97	6.78
	2005	12,852	16,848	103,854	1.31	6.16	8.08
	2006	10,645	13,777	91,839	1.29	6.67	8.63
	2007	9,632	12,199	88,674	1.27	7.27	9.21
	2008	6,988	8,499	68,068	1.22	8.01	9.74
	2009	4,375	5,424	43,461	1.24	8.01	9.93
	2010	2,466	2,937	27,939	1.19	9.51	11.33

**Table 2. Number of Incident Lindane Users, Dispensings, and Total Days Supplied, Dispensings per User, Days per Dispensing and Days per User by Age Group and Sex, and Year (2000-2010)**

		Users	Dispensings	Days Supplied	Dispensings per User	Days Supplied per Dispensing	Days Supplied per User
<b>Overall</b>		<b>112,696</b>	<b>183,741</b>	<b>1,142,091</b>	<b>1.63</b>	<b>6.22</b>	<b>10.13</b>
Age group	0 to 1 years	1,109	2,008	10,258	1.81	5.11	9.25
	2 to 4 years	8,815	16,825	91,244	1.91	5.42	10.35
	5 to 9 years	20,884	38,733	222,162	1.85	5.74	10.64
	10 to 14 years	16,856	28,779	165,476	1.71	5.75	9.82
	15 to 18 years	7,973	11,513	69,832	1.44	6.07	8.76
	19 to 21 years	4,441	6,234	42,786	1.40	6.86	9.63
	22 to 44 years	28,463	44,485	279,621	1.56	6.29	9.82
	45 to 64 years	16,783	25,361	181,467	1.51	7.16	10.81
	65 to 74 years	3,520	4,831	37,968	1.37	7.86	10.79
75+ years	3,852	4,972	41,277	1.29	8.30	10.72	
Sex	Female	76,455	129,781	798,726	1.70	6.15	10.45
	Male	36,130	53,808	342,408	1.49	6.36	9.48
	Unknown	111	152	957	1.37	6.30	8.62
Year	2000	26,913	36,208	219,557	1.35	6.06	8.16
	2001	26,478	35,535	253,805	1.34	7.14	9.59
	2002	17,701	24,593	132,270	1.39	5.38	7.47
	2003	14,145	19,857	102,896	1.40	5.18	7.27
	2004	13,050	18,048	85,792	1.38	4.75	6.57
	2005	11,079	14,486	88,104	1.31	6.08	7.95
	2006	9,004	11,671	77,803	1.30	6.67	8.64
	2007	7,191	9,115	64,538	1.27	7.08	8.97
	2008	5,867	7,062	55,553	1.20	7.87	9.47
	2009	3,720	4,596	36,948	1.24	8.04	9.93
	2010	2,069	2,448	23,570	1.18	9.63	11.39

Figure 1. Number of Prevalent and Incident Lindane Dispensings between January 1, 2000 through May 31, 2011

