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History Of Singulair And Psychiatric Adverse Reactions In Canada: 1997 - January 2009

July 2009 *Canadian Adverse Reaction Newsletter* Provides Summary Of Reports Made To Health Canada

(Posted by Tom Lamb at www.DrugInjuryWatch.com on 07/14/09; see http://bit.ly/Nsu6D)

Singulair (montelukast) has been marketed in Canada since 1997. In Canada Singulair is indicated for: (1) the prophylaxis and chronic treatment of asthma in patients 2 years of age or older; and, (2) the relief of symptoms of seasonal allergic rhinitis in patients 15 years of age and older when other treatments are not effective or not tolerated.

In the July 2009 edition of The Canadian Adverse Reaction Newsletter (CARN) there appears an article, "Montelukast (Singulair): suicidality and other psychiatric adverse reactions", which provides a summary of reports made to Health Canada from 1997 through January 31, 2009.

From this July 2009 CARN article:

> From the date of marketing to Jan. 31, 2009, Health Canada received 13 adverse reaction (AR) reports related to suicidality or self-injury suspected of being associated with the use of [Singulair (montelukast)]. Eight reports stated that the reaction abated after the dose was reduced or the drug was stopped. The reaction reappeared after the reintroduction of [Singulair] in 1 case. All but 1 of the reports were received by Health Canada after the FDA's early communication [in March 2008].
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> From the date of marketing to Jan. 31, 2009, Health Canada received 29 other AR reports relating to depression, hostility or psychosis suspected of being associated with the use of [Singulair (montelukast)]. In 19 cases, the reaction abated after [Singulair] was stopped or the dose was reduced. The reaction reappeared after the reintroduction of [Singulair] in 4 cases. Thirteen of the 29 reports were received by Health Canada after the FDA's early communication [in March 2008].
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> No deaths were reported in any of the cases discussed above. Twenty-six of the 42 reports involved patients under 18 years of age (age was not indicated in 5 reports).

In the U.S. the FDA announced in June 2009 that it was requiring a new warning about an increased risk of neuropsychiatric events for Singulair.

This FDA announcement about Singulair was followed closely by a medical journal article, "Montelukast and psychiatric disorders in children.", which was published in the June 23, 2009 edition of Pharmacoepidemiology and Drug Safety. The Abstract for this article starts: "A signal has been raised concerning [Singulair (montelukast)] and adverse drug reactions (ADRs) in children."

We will continue to monitor and report about neuropsychiatric events in adults and children using this popular asthma drug Singulair, from Merck & Co.

Attorney Tom Lamb represents people in personal injury and wrongful death cases involving unsafe prescription drugs or medication errors. The above article was posted originally on his blog, **Drug Injury Watch** – with live links and readers' Comments.
http://www.DrugInjuryWatch.com