PROGRAMME DES PRODUITS THÉRAPEUTIQUES
THERAPEUTIC PRODUCTS PROGRAMME

Status of Astemizole (Hismanal ™) in Canada

What is astemizole?

Astemizole is the name of the active ingredient in a drug taken by mouth to relieve allergy symptoms. Astemizole belongs to a group of drugs called the non-sedating, second generation antihistamines. Second generation antihistamines differ from other antihistamines in that they may cause less drowsiness and less impairment of intellectual and motor functions.

Under which brand names could astemizole products be identified in Canada?

Hismanal™ was the only astemizole containing-product available in Canada. Hismanal™ was sold by the manufacturer in Canada between 1985 and 1999.

When did the sale of astemizole cease in Canada?

In March 1999, Johnson & Johnson ᴎ Merck Consumer Pharmaceuticals, the manufacturer authorized to sell astemizole (Hismanal™) in Canada, provided notice to the Therapeutic Products Programme (TPP) that it was voluntarily cancelling its Drug Identification Number (DIN) and thereby ceasing the sale of Hismanal™ in Canada.

What is the status of astemizole in the USA?

In June 1999, Janssen Pharmaceutica, the originator of the product, announced publicly in the USA that it was "voluntarily withdrawing the prescription antihistamine, Hismanal™ (Astemizole) 10 mg, from the market"[1].

[1]U.S. Food and Drug Administration. Janssen Pharmaceutica announces the withdrawal of Hismanal from the market. Media Release: [1 page], June 21, 1999. Available from http://www.fda.gov - USA

Have there been any safety concerns associated with the use of astemizole?

Use of astemizole with certain other drugs or foods and in certain medical conditions is associated with the potential to result in rare and serious cardiac side effects primarily involving changes in heart rhythm. Some commonly prescribed antibiotics and some treatments for fungal infections are known to increase blood levels of astemizole by affecting the way the body handles astemizole products. Other drugs and foods such as grapefruit juice may have a similar potential to alter blood levels of astemizole until reaching an astemizole toxic blood level, thereby predisposing to rare and serious cardiac side effects.

Another concern is that Canadians may self-diagnose allergic symptoms and take “on hand” antihistamines without consulting with a health care professional such as a dentist, nurse, pharmacist or physician regarding newly identified drug interactions, food interactions or other health risks.

Why are the drugs identified as having the potential to interact adversely with astemizole are not listed?

The list of drugs having the potential to interact adversely with astemizole is continuously growing. In addition, not all marketed drugs have been tested for the astemizole interaction.

What was done to address these safety concerns? If it was a risk, why was it allowed on the market previously ?

As new information about marketed products is continuously gathered, it is used to update the drug’s safety information. It is through experience in the market that additional safety information becomes available. Astemizole was initially approved as a prescription drug in 1984. It was marketed in Canada in 1985. It became over-the-counter (OTC) in 1986 for adults.

In 1992, controls on the availability of astemizole as a non-prescription drug were increased to address new identified concerns. These controls started with astemizole being placed behind the pharmacy counter, to be purchased only after discussion with a pharmacist.

Over subsequent years, there was extensive revision of the official Product Monograph regarding newly identified safety concerns. In 1997, a Dear Doctor Letter was issued by Health Canada to all Canadian pharmacists, physicians and surgeons advising them of safety concerns and notifying them of the decision to return Hismanal™ from non-prescription (behind the pharmacy counter) to prescription status, which meant that consumers had to consult with a physician in order for the drug to be prescribed.

However, since this time there has been a continuous increase in the number of drugs identified as having the potential to interact adversely with astemizole thereby increasing the risk for rare and serious cardiac side effects.

Why is Health Canada providing this information now?

The TPP of Health Canada is providing this notice now in order to clarify the status of astemizole in Canada. The TPP reminds health care professionals and consumers that astemizole no longer has a valid DIN number and that the manufacturer has ceased the sale of this drug in Canada.

Has there been any action taken to remove this product from pharmacy shelves?

In September 1999, Johnson & Johnson N Merck Consumer Pharmaceuticals withdrew all remaining inventories of Hismanal™ from the market and asked that pharmacists return existing inventories[2].

[2] Ulana Kopystansky, Editor Advisor. Announcement Concerning Hismanal. *Pharmacy Bulletin Board* September 13, 1999: 1.

What should be done with any leftover astemizole from a previous prescription?

Any astemizole (Hismanal™) that is left over should be returned to a pharmacy for disposal.

How can Canadians be certain that a health product does not contain astemizole?

Canadians should always read the label on every health product before taking it. If in doubt, they should consult with their health care professional. Another option is to directly contact the drug manufacturer.

Are there other second generation anti-histamines available on the market ?

There are other second generation antihistamines taken by mouth which are sold in Canada to relieve allergy symptoms.

Canadians should consult with a health care professional to find the most appropriate choice for them.

What other treatments are available in Canada to relieve allergy symptoms?

Canadians are encouraged to seek advice from their health care professional prior to choosing therapies to relieve allergy symptoms to make sure there are no contraindications for such health products and no interactions with other health products or foods that they may be taking.

What should Canadians do if they have a suspected side effect to any health product?

Canadians should inform a health care professional if they have a suspected side effect to any health product.

Health care professionals should report any side effects suspected to be associated with health product use to the TPP through either their Regional Adverse Drug Reaction Reporting Centre[3] or directly to the Canadian Adverse Drug Reaction Monitoring Programme office[4] in Ottawa . Another option is to directly contact the drug manufacturer.

[3] **British Columbia**, BC Regional ADR Centre, E-mail: adr@dpic.bc.ca; **Saskatchewan**, Sask ADR Regional Centre, E-mail: vogt@duke.usask.ca; **Ontario**, Ontario Regional ADR Centre, E-mail: adr@lhsc.on.ca; **Québec**, Quebec Regional ADR Centre, E-mail: cip.hscm@sympatico.ca; **N ova Scotia, New Brunswick, Newfoundland and Prince Edward Island**, Atlantic Regional ADR Centre, E-mail: RXKLS1@qe2-hsc.ns.ca.

[4] **All other Provinces and Territories,** National ADR Reporting Unit, E-mail: cadrmp@hc-sc.gc.ca.

What is Health Canada doing to protect the health and safety of Canadians?

The TPP of Health Canada develops the regulations, sets the standards, and approves the manufacturing and sale of therapeutic products. The TPP has to be satisfied that drugs and medical devices meet Canadian standards, standards which often surpass accepted international standards, before any therapeutic product is made available to Canadians.

For Further Information

Write:

Adverse Reaction Information Unit
Bureau of Licensed Product Assessment
Therapeutic Products Programme
Health Canada
Tunney's Pasture
Address Locator 0201C1
Ottawa, Ontario
K1A 1B9
Telephone: (613) 957-0337
Facsimile: (613) 957-0335

or visit our website:

www.hc-sc.gc.ca/hpb-dgps/therapeut

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The Therapeutic Products Programme is the national authority that evaluates and monitors the safety, effectiveness, and quality of drugs, medical devices and other therapeutic products available to Canadians.

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