Status
of Terfenadine-Containing Drugs in Canada

What is terfenadine?

Terfenadine is the name of the active ingredient in a drug taken by mouth to relieve allergy symptoms. Terfenadine 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 terfenadine-containing drugs be identified in Canada?

There were many brand names under which terfenadine-containing drugs were available. This list may not be all inclusive and is for information purposes only. If Canadians require more information, they should see a health care professional such as a dentist, nurse, pharmacist or physician.

Allergy Relief
Allergy Relief Once a Day Allergy
Apo®-Terfenadine
Big V Allergy Relief
Big V Once a Day Allergy
Contac® Allergy Formula
Contac® formule antiallergique
Guardian Allergy Relief
IDA Allergy Relief
Life Terfenadine
London Drugs Once A Day Allergy
Novo-Terfenadine
Once A Day Terfenadine
Option + Terfenadine
Option Plus Once A Day Allergy
Personnelle Allergy Relief
Personnelle Once A Day Allergy
Pharma Plus Once A Day Allergy
Pharma Plus Terfenadine
When did the sale of terfenadine-containing drugs cease in Canada?

By the end of 1999, all the manufacturers authorized to sell terfenadine-containing drugs in Canada provided notice to the Therapeutic Products Programme (TPP) that they were voluntarily cancelling their Drug Identification Numbers (DINs) and thereby ceasing the sale of terfenadine-containing drugs in Canada.

What is the status of terfenadine in the USA?

In 1998, Hoechst Marion Roussel and Baker Norton Pharmaceuticals, respectively the originator of the terfenadine-containing drug and its generic formulation “voluntarily discontinued distribution and marketing of all terfenadine-containing antihistamine product lines in the United States”.


Have there been any safety concerns associated with the use of terfenadine-containing drugs?

Use of terfenadine-containing drugs 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 terfenadine by affecting the way the body handles terfenadine-containing drugs. Other drugs and foods such as grapefruit juice may have a similar potential to alter blood levels of terfenadine until reaching a terfenadine 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 regarding newly identified drug interactions, food interactions or other health risks.
Why are the drugs identified as having the potential to interact adversely with terfenadine are not listed?

The list of drugs having the potential to interact adversely with terfenadine-containing drugs is continuously growing. In addition, not all marketed drugs have been tested for the terfenadine 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. Terfenadine was initially marketed in Canada in 1983.

In 1992, controls on the availability of terfenadine-containing drugs as non-prescription drugs were increased to address newly identified concerns. These controls started with the terfenadine-containing drugs 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 change terfenadine-containing drugs from non-prescription (behind the pharmacy counter) to prescription status, which meant that consumers had to consult with a physician 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 terfenadine-containing drugs, 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 terfenadine-containing drugs in Canada. The TPP reminds health care professionals and consumers that these terfenadine-containing drugs no longer have valid DIN numbers and that their manufacturers have ceased the sale of these drugs in Canada.

What should be done with any leftover terfenadine-containing drugs from a previous prescription?

Any terfenadine-containing drugs that are left over, should be returned to a pharmacy for disposal.

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

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 antihistamines available on the market?

There are other second generation antihistamines taken by mouth which are sold in Canada for the relief of 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 adverse event suspected to be associated with health product use to the TPP through either their Regional Adverse Drug Reaction Reporting Centre or directly to the Canadian Adverse Drug Reaction Monitoring Programme office in Ottawa. Another option is to directly contact the drug manufacturer.

2 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; Quebec, Quebec Regional ADR Centre, E-mail: cip.hscm@sympatico.ca; Nova Scotia, New Brunswick, Newfoundland and Prince Edward Island, Atlantic Regional ADR Centre, E-mail: RXKLS1@qe2-hsc.ns.ca.

3 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.