

Update on the rifampin drug shortage

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Starting date: March 15, 2020
Type of communication: Advisory
Subcategory: Drugs
Source of recall: Health Canada
Issue: Supply
Audience: General Public
Identification number: RA-72601

Last updated: 2020-03-15

March 15, 2020

For immediate release

Summary

Product: Rofact (Rifampin)

Issue: Bausch Health, Canada Inc. is releasing a limited number of lots of its tuberculosis drug rifampin (Rofact), to mitigate a national shortage. Although these lots contain slightly higher than acceptable levels of a nitrosamine impurity, the risks of not being treated immediately are greater than would result from short term use of the drug.

What to do: Do not stop taking your rifampin without first discussing treatment options with your health care provider. The risks from not treating your tuberculosis outweigh the risks from exposure to the nitrosamine impurity found in Bausch's rifampin product.

Issue

Health Canada is providing Canadians with an update on the domestic supply of rifampin and efforts to mitigate the shortage in Canada.

Rifampin is the primary drug used to treat pulmonary tuberculosis, a critical health condition. There are two authorized suppliers of rifampin in Canada: Bausch Health, Canada Inc. (Bausch) markets Rofact and Sanofi-Aventis Canada Inc. (Sanofi) markets Rifadin. Both have reported shortages of their products.

Sanofi reported a shortage beginning on July 3, 2019, because of a production delay and an increase in demand, and has no remaining stock. Sanofi has not confirmed when it will be able to resolve its shortage. Bausch reported a shortage beginning on January 10, 2020, as a result of delays in obtaining an active pharmaceutical ingredient supplier.

Health Canada is aware of the strain that shortages can place on patients and the health care system. When national drug shortages occur, the Department assesses their severity and potential impact on Canadians. Health Canada works closely with the Canadian companies that supply drugs, the provinces and territories, and health stakeholders across the supply chain to identify and facilitate mitigation measures, as needed.

In this case, given the significant impact this shortage could have on patients and the health care system, Health Canada assessed Bausch's proposal to release five lots of ROFACT 300mg (8,723 units) and two lots of ROFACT 150mg (1,908 units) that contain the nitrosamine impurity, 1-nitroso-4-methyl piperazine, at a level that is slightly above the acceptable limit (they contain 2.2 parts per million [ppm], which is marginally higher than the limit of 2.1 ppm). Bausch reports that these lots are available in the Canadian market as of March 13, 2020. As a result, Bausch expects to meet demand by March 16.

This is an interim measure to mitigate this shortage and Bausch is working to produce new batches of rifampin that fall within the acceptable limit for this impurity.

Based primarily on animal studies, nitrosamine impurities are classified as a probable or possible human carcinogen. We are all exposed to low levels of nitrosamines through a variety of foods (such as smoked and cured meats, dairy products and vegetables), drinking water and air pollution.

Nitrosamines are not expected to cause harm when ingested at low levels. Since patients would be at much greater risk from untreated disease and rifampin is typically taken for relatively short periods (nine months to one year), the very low increased lifetime risk of cancer is outweighed by the need for immediate critical treatment.

In addition, Health Canada continues to work with international regulatory agencies to make a determination on long-term acceptable limits for nitrosamine impurities in drugs and will communicate any changes to the acceptable limits for nitrosamine impurities to manufacturers and Canadians in a timely manner.

While Health Canada is the federal regulator responsible for the safety, efficacy and quality of health products in Canada, companies are ultimately responsible for the supply of their products.

For more information on drug shortages and Health Canada's role, consult the [Drug Shortages in Canada section of the Canada.ca website \(https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-shortages.html\)](https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-shortages.html).

For additional information regarding these specific shortages, visit the [Drug Shortages Canada website \(https://www.drugshortagescanada.ca/\)](https://www.drugshortagescanada.ca/) or contact the company directly:

- Bausch Health, Canada Inc., Canada Medical Information, 1-800-361-4261
- Sanofi-Aventis Canada Inc.: 1-800-265-7927

What consumers should do

Do not stop taking your rifampin without first discussing treatment options with your health care provider. The risks from not treating your tuberculosis outweigh the risks from exposure to the nitrosamine impurities found in Bausch's rifampin products.

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Date modified: 2020-03-15