

Summary Safety Review - Cephalosporins - Assessing the Potential Risk of Seizures

Product: Cephalosporins (cephalexin-, cefazolin-, cefadroxil-, cefoxitin-, cefuroxime-, cefprozil-, cefotaxime-, ceftazidime-, ceftriaxone-, cefixime-, cefepime-, ceftobiprole- and ceftolozane-tazobactam-containing products)

Potential Safety Issue: Seizures

Key Messages

- **Cephalosporins are a group of prescription antibiotic drugs authorized for sale in Canada to treat a wide range of bacterial infections, including urinary and respiratory tract infections.**
- **Health Canada reviewed the potential risk of seizures with the use of cephalosporins. The safety review was triggered by a labelling update for a cefazolin-containing product marketed in the United States (U.S.).**
- **Health Canada’s review concluded that there may be a link between the use of cephalosporins and the risk of seizures.**
- **At the time of the safety review, the risk of seizures was already included in the product safety information in the Canadian product monograph (CPM) for some cephalosporins. Health Canada will work with the manufacturers to update the CPM for the cephalosporins that do not already include this risk.**

Overview

Health Canada reviewed the potential risk of seizures with the use of cephalosporins. This safety review was triggered by a U.S. Food and Drug Administration update to the product safety information for a cefazolin-containing product to include the risk of seizures.

Use in Canada

- Cephalosporins are a group of prescription antibiotic drugs authorized for sale in Canada to treat a wide range of bacterial infections, including urinary and respiratory tract infections.
- Cephalosporins have been marketed in Canada for over 50 years under different brand names and generics of cephalexin, cefazolin, cefadroxil, cefoxitin, cefuroxime, cefprozil, cefotaxime, ceftazidime, ceftriaxone, cefixime, cefepime, ceftobiprole, and ceftolozane-tazobactam.
- Cephalosporins are a widely prescribed group of antibiotic drugs, with approximately 3.6 million prescriptions filled in Canadian retail pharmacies every year.

Safety Review Findings

- Health Canada reviewed the available information from searches of the Canada Vigilance database^a, international databases, as well as medical and scientific literature.
- Health Canada reviewed 84 cases (7 Canadian and 77 international) of seizures in patients taking cephalosporins. Of the 84 cases, 13 were found to be probably linked to the use of cephalosporins. Sixty-two cases (4 Canadian) were found to be possibly linked, and 3 cases were unlikely to be linked to the use of cephalosporins. Six cases (3 Canadian) could not be assessed.

Conclusions and Actions

- Health Canada’s review of the available information concluded that there may be a link between the use of cephalosporins and the risk of seizures.
- At the time of the safety review, the risk of seizures was already included in the CPM for some cephalosporins. Health Canada will work with the manufacturers to update the CPM for the cephalosporins that do not already include this risk.
- Health Canada encourages consumers and healthcare professionals to [report](#) any side effects related to the use of cephalosporins and other health products to the [Canada Vigilance Program](#).
- Health Canada will continue to monitor safety information involving cephalosporins, as it does for all health products on the Canadian market, to identify and assess potential harms. Health Canada will take appropriate and timely action should new health risks be identified.

Additional Information

The analyses that contributed to this safety review included scientific and medical literature, Canadian and international information, and what is known about the use of cephalosporins both in Canada and internationally.

For additional information, [contact the Marketed Health Products Directorate](#).

a. Canadian reports can be accessed through the [Canada Vigilance Online Database](#).