Health Canada Santé Canada

Canada

Health Product InfoWatch

January 2024

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REPORTING ADVERSE REACTIONS

Canada Vigilance Program
Online: Adverse Reaction and Medical Device Problem Reporting
Telephone: 1-866-234-2345
Fax or mail: Form available online

SUBSCRIBE

To receive the Health Product InfoWatch and notifications of health product advisories electronically, subscribe to MedEffect™ e-Notice or to MedEffect™ Canada RSS feeds.

This monthly publication is intended primarily for healthcare professionals and includes information on pharmaceuticals, biologics, medical devices and natural health products. It provides a summary of key health product safety information published in the previous month by Health Canada, as well as a selection of new health product safety information meant to raise awareness. New information contained in this issue is not comprehensive but rather represents a selection of clinically relevant items warranting enhanced dissemination.

MONTHLY RECAP OF HEALTH PRODUCT SAFETY INFORMATION

The following is a list of health product advisories, type I drug recalls and summaries of completed safety reviews published in December 2023 by Health Canada.

0.9% Sodium Chloride Injection, USP Type 1 drug recall	Baxter Corporation recalled additional affected lots of 0.9% Sodium Chloride Injection, USP as the solution bags may be leaking.
Bleomycin for Injection USP Type 1 drug recall	One lot of Bleomycin for Injection USP was recalled as the affected lot may contain glass particulate.
JAMP Guanfacine XR Advisory Type 1 drug recall	JAMP Pharma Corporation recalled one lot of JAMP Guanfacine extended release (XR) 1 mg tablets because some bottles may contain JAMP Guanfacine XR 4 mg tablets in addition to the correct strength of 1 mg tablets. Patients taking a 4 mg tablet instead of a prescribed 1 mg tablet will unexpectedly receive a higher dose than intended, which may result in overdose and could pose serious health risks.
Unauthorized health products Unauthorized injectable drug products sold online by Canlab Research Unauthorized sexual enhancement products Unauthorized skin lightening and skin treatment products Unauthorized workout supplements	Health Canada advised Canadians about various unauthorized health products being sold at retail locations across Canada or online that may pose serious health risks.

NEW HEALTH PRODUCT SAFETY INFORMATION

The following topics have been selected to raise awareness and encourage reporting of adverse reactions.

Product monograph updates

The following safety labelling updates, which were recently made to the Canadian product monographs, have been selected for your awareness. A complete list of safety labelling updates for pharmaceuticals is available on Health Canada's Product monograph brand safety updates page. Canadian product monographs can be accessed through Health Canada's Drug Product Database.

Plaquenil (hydroxychloroquine sulfate)

The *Warnings and Precautions* section of the Canadian product monograph for Plaquenil has been updated with the following risks: **drug-induced phospholipidosis** in specific organs, **hepatotoxicity, hepatitis B virus reactivation** and **aggravation of myasthenia gravis**.

Key messages for healthcare professionals:[1]

Drug-induced phospholipidosis

- Cardiomyopathy:
  - In multiple cases of cardiomyopathy in patients treated with Plaquenil, endomyocardial biopsy showed an association with phospholipidosis in the absence of inflammation, infiltration, or necrosis.
  - Monitor cardiac function as clinically indicated during therapy.
  - Discontinue Plaquenil if cardiotoxicity is suspected or demonstrated by tissue biopsy.
- Skeletal Muscle Myopathy or Neuropathy:
  - Muscle and nerve biopsies have shown associated phospholipidosis.
  - Monitor muscle strength and deep tendon reflexes during therapy.
  - Discontinue Plaquenil if muscle or nerve toxicity is suspected or demonstrated by tissue biopsy.
- Drug-induced phospholipidosis may also occur in other organ systems.

Hepatotoxicity

- Serious cases of drug-induced liver injury including hepatocellular injury, cholestasis, acute hepatitis and fulminant hepatic failure (including fatal cases) have been reported during use of Plaquenil. Healthcare professionals should assess the benefits/risk of continuing the treatment in patients with significant liver function abnormalities.

Hepatitis B virus reactivation

- The reactivation of hepatitis B virus has been reported in patients treated with hydroxychloroquine administered individually or more often in combination with other immunosuppressants.

Aggravation of Myasthenia Gravis

- Aggravation of symptoms of myasthenia gravis (i.e., weakness of the skeletal muscles, shortness of breath, dysphagia, diplopia etc.) has been reported in myasthenic patients receiving hydroxychloroquine therapy.

Reference

1. *Plaquenil (hydroxychloroquine sulfate)* [product monograph]. Laval (QC): sanofi-aventis Canada Inc.; 2023.

Prolia (denosumab)

The *Indications, Warnings and Precautions, Adverse Reactions (Post-Market Adverse Reactions), Clinical Pharmacology (Pharmacokinetics, Special Populations and Conditions),* and *Patient Medication Information* sections of the Canadian product monograph for Prolia have been updated with additional information on the risk of **severe symptomatic hypocalcemia** and **safety in pediatric patients**.

Key messages for healthcare professionals:[1]

Hypocalcemia

- In the post-market setting, severe symptomatic hypocalcemia (resulting in hospitalization, life-threatening events and fatal cases) has been reported, particularly in patients with severe renal impairment, receiving dialysis or treatment with other calcium-lowering drugs.
- While most cases occurred in the first weeks of initiating therapy, it can also occur later. Examples of the clinical manifestations of severe symptomatic hypocalcemia have included QT interval prolongation, tetany, convulsions and altered mental status.
- Patients should be advised to report to their physicians any symptoms of hypocalcemia, such as paresthesias or muscle spasms, twitching and muscle cramps.

Pediatrics

- Based on the data submitted and reviewed by Health Canada, the safety and efficacy of Prolia in pediatric patients has not been established; therefore, Health Canada has not authorized an indication for pediatric use.
- In clinical trials, hypercalcemia has been reported in pediatric patients with osteogenesis imperfecta treated with denosumab. Some cases required hospitalization and were complicated by acute renal injury.

Reference

1. *Prolia (denosumab)* [product monograph]. Mississauga (ON): Amgen Canada Inc., 2023.

Propecia (finasteride, 1 mg) and Proscar (finasteride, 5 mg)

The *Warnings and Precautions* and *Patient Medication Information* sections of the Canadian product monographs for Propecia and Proscar have been updated with the risk of **mood alterations including depressed mood, depression, self-harm injury and suicidal ideation**.

Key messages for healthcare professionals:[1,2]

- There have been post-marketing reports of serious psychiatric symptoms in patients treated with finasteride that sometimes continued after treatment discontinuation. Mood alterations including depressed mood, depression, self-harm injury, suicidal ideation, as well as worsening of pre-existing depression have been reported in patients treated with finasteride.

- It is recommended that all patients be screened for suicidal ideation, self-harm, and depression and/or associated risk factors before treatment initiation.
- Clinical monitoring of all patients for signs and symptoms of psychiatric disorders should continue throughout treatment and afterward.
- Propecia: If these symptoms occur, treatment should be discontinued and patients advised to seek medical advice as soon as possible.
- Proscar: If these symptoms occur, patients should be advised to seek medical advice as soon as possible.

References

1. *Propecia (finasteride film-coated tablets 1 mg, USP)* [product monograph]. Kirkland (QC): Organon Canada Inc., 2023.
2. *Proscar (finasteride film-coated tablets 5 mg, USP)* [product monograph]. Kirkland (QC): Organon Canada Inc., 2023.

Helpful links

- MedEffect™ Canada
- Recalls and Safety Alerts Database
- New Safety and Effectiveness Reviews
- Canada Vigilance Adverse Reaction Online Database
- Drug Product Database
- Medical Devices Active Licence Listing
- Licensed Natural Health Products Database
- The Drug and Health Product Portal
- Drug Shortages Canada
- Medical device shortages: List of shortages and discontinuations
- Stop Illegal Marketing of Drugs and Devices
- List of drugs for exceptional importation and sale
- Coronavirus disease (COVID-19)
- Drug and vaccine authorizations for COVID-19: List of authorized drugs, vaccines and expanded indications
- COVID-19 vaccines and treatments portal
- Reported side effects following COVID-19 vaccination in Canada

Suggestions?

Your comments are important to us. Let us know what you think by reaching us at: infowatch-infovigilance@hc-sc.gc.ca

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Adverse reactions (ARs) to health products are considered to be suspicions, as a definite causal association often cannot be determined. Spontaneous reports of ARs cannot be used to estimate the incidence of ARs because ARs remain underreported and patient exposure is unknown.

Due to time constraints relating to the production of this publication, information published may not reflect the most current information.

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