Health Canada Santé Canada

Canada

Health Product InfoWatch

July 2025

Contents

REPORTING ADVERSE REACTIONS

Canada Vigilance Program
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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 June 2025 by Health Canada.

0.9% Sodium chloride injection, USP

Baxter Corporation recalled 1 lot of 0.9% Sodium chloride injection, USP as the solution bags may be leaking.

Type I drug recall: 0.9% Sodium Chloride Injection, USP

Accel-Ondansetron ODT

Following a recall in June 2024, Health Canada has reviewed the bioequivalence test data provided by Accel Pharma Inc., and has confirmed that Accel-Ondansetron ODT (4 mg and 8 mg tablets) are equivalent to their brand name counterparts and are safe and effective to use. As a result, the company has resumed the sale of undistributed units from lots CDX00123 and CEA00123.

Advisory: Accel-Ondansetron ODT
Type I drug recall: Accel-Ondansetron ODT

Fluoxetine

Affected lots of fluoxetine 10 mg capsules have been recalled as they may exceed the interim acceptable intake limit for N-nitroso-fluoxetine.

Type I drug recall: PMS-Fluoxetine
Type I drug recall: PRO-Fluoxetine

Nitric Oxide and Treprostinil

This safety review evaluated the risk of pulmonary edema in patients with pulmonary veno-occlusive disease with the use of either nitric oxide- or treprostinil-containing products. Health Canada's review found a possible link. Health Canada will work with the manufacturers to update the Canadian product monograph for all nitric oxide- and treprostinil-containing products to include this risk.

Summary Safety Review: Nitric Oxide and Treprostinil

Oracare Baby Brush toothbrush

Health Canada advised consumers about a recall of the Oracare Baby Brush toothbrush sold at Dollarama stores across Canada. The toothbrush may pose a choking hazard due to a manufacturing defect that can cause it to break into 2 pieces.

Advisory: Oracare Baby Brush toothbrush
Type II medical device recall: Oracare Baby Brush toothbrush

Seasonale (levonorgestrel and ethinyl estradiol tablets)

Teva Canada Ltd. recalled 2 lots of Seasonale prescription birth control after receiving a complaint that a package contained an extra row of placebo (white) pills where there should be none. Taking placebo pills instead of active (pink) pills may reduce the effectiveness of the product and could lead to an unintended pregnancy.

Advisory: Seasonale (levonorgestrel and ethinyl estradiol tablets)
Type I drug recall: Seasonale (levonorgestrel and ethinyl estradiol tablets)

Seasonique (levonorgestrel and ethinyl estradiol tablets, and ethinyl estradiol tablets)

Teva Canada Ltd. recalled 1 lot of Seasonique prescription birth control due to the possibility of having an extra row of yellow pills in tray 1 and/or 2 of the blister cards, where there should be none. This may increase the risk of pregnancy.

Advisory: Seasonique (levonorgestrel and ethinyl estradiol tablets, and ethinyl estradiol tablets)
Type I drug recall: Seasonique (levonorgestrel and ethinyl estradiol tablets, and ethinyl estradiol tablets)

Unauthorized Health Products

Health Canada advised Canadians about various unauthorized health products being sold at retail locations across Canada or online that may pose serious health risks.

Advisory: Unauthorized blood glucose monitors sold online
Advisory: Unauthorized sexual enhancement products
Advisory: Various unauthorized nitrous oxide products

Virility for Men (Yi Li Xiao Capsule)

Health Canada warned consumers not to use Virility for Men (Yi Li Xiao Capsule) because it may pose serious health risks. The product was authorized as a natural health product, but recent Health Canada testing found it contains tadalafil, a prescription drug used to treat erectile dysfunction, which was not listed on the product label. Health Canada has suspended the product licence and the licence holder, Yexin Likang International Health Inc., recalled the product, which was distributed in Ontario.

Advisory: Virility for Men (Yi Li Xiao Capsule)
Type I drug recall: Virility for Men (Yi Li Xiao Capsule)

NEW HEALTH PRODUCT SAFETY INFORMATION

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

Product monograph and medical device instructions for use updates

The following safety labelling updates, which were recently made to the Canadian product monograph and medical device instructions for use, have been included 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.

Nexavar (sorafenib)

The *Warnings and Precautions, Adverse Reactions (Post-Market Adverse Reactions)* and *Patient Medication Information* sections of the Canadian product monograph for Nexavar have been updated with the risk of **tumour lysis syndrome (TLS).**

Key messages for healthcare professionals:[1]

- Cases of TLS, some fatal, have been reported in post-marketing surveillance in patients treated with sorafenib.
- Risk factors for TLS include high tumour burden, pre-existing chronic renal insufficiency, oliguria, dehydration, hypotension, and acidic urine.
- These patients should be monitored closely and treated promptly as clinically indicated; prophylactic measures should be considered if clinically indicated.

Reference

1. *Nexavar (sorafenib)*[product monograph]. Mississauga (ON): Bayer Inc.; 2025.

MEGA SOFT Reusable Patient Return Electrodes

MEGA SOFT Reusable Patient Return Electrodes (product codes: 0830, 0835, 0845, 0846, 0847, and 0848) are designed to be used whenever monopolar electrosurgery is indicated. The intended use of these devices is to conduct monopolar electrosurgical energy from target tissue of a patient back to one or two electrosurgical units, or generators.[1-3]

Health Canada has received reports of patient burns following surgical procedures in which MEGA SOFT pads were used. Since June 2023, the manufacturer, Megadyne Medical Products Inc., has initiated 4 voluntary recalls for various product codes. In July 2024, in collaboration with Health Canada, the company issued a Health professional risk communication to help mitigate the risk.[4] The impact of burn injuries may be greater in pediatric patients than in adults; therefore, the intended use population has been revised.

All MEGA SOFT pads including MEGA SOFT (product codes: 0830 and 0835), MEGA SOFT Universal (product codes: 0845 and 0846), and MEGA SOFT Universal Plus (product codes: 0847 and 0848) are now limited to **use in patients aged 12 years or older**. Additional sections in the Instructions For Use (IFUs), including: *To*

Install the Patient Return Electrode; Cleaning, Disinfection, and Care Instructions; *Repair*; *Heating and Cooling; Warnings*; *Cautions*; and the *Compatibility Statement* were also updated to reduce the risk of **burn injury**.

Key messages for healthcare professionals:[1-4]

- Healthcare facilities may have unexpired pads labelled *>25 lbs (>11.3 kg)* for product codes 0830 and 0835, and *>0.35 kg (>0.8 lbs)* for product codes 0845, 0846, 0847 and 0848. Regardless of the labelling on the pad, all MEGA SOFT pads are now restricted to **use in patients aged 12 years or older**.
- Healthcare facilities that currently have unexpired pads should verify receipt of the manufacturer's customer letter dated April 2025, which provides important information on the updated Canadian IFUs, including links (QR codes) to the updated IFUs; as well as updated versions of the Placement and Setup Brochure, the Cleaning and Care Brochure, and the Optimized Device Performance Guide.
- Starting in April 2025, the manufacturer began distributing new pads with updated on-device labelling reflecting the revised intended use population of **age ≥ 12 years** for product codes 0845, 0846, 0847 and 0848. Product codes 0830 and 0835 have been discontinued and no longer shipped to customers after March 2024.

Healthcare professionals are advised to:

- Review the updated IFUs, paying particular attention to the updated intended use population of **patients aged 12 years and older**. Pads should not be used on neonatal patients, infants, or children under the age of 12 years.
- Follow the updated device IFUs, especially the instruction **not** to place any materials between the patient and the MEGA SOFT pads.
- Adhere to the guide in the updated Placement and Setup Brochure, Cleaning and Care Brochure, and the Optimized Device Performance Guide.
- Pay attention to the expiration date of the pads. The MEGA SOFT pads are intended for use as 24-month reusable patient return electrodes.
- Contact the manufacturer for any questions or concerns.

References

1. *MEGA SOFT™ Reusable Patient Return Electrode & MEGA SOFT™ Dual Reusable Patient Return Electrode* (Product code 0830 and 0835) [Instructions For Use]. Cincinnati (OH): MEGADYNE Medical Products, Inc., March 2025. https://www.e-ifu.com/
2. *MEGA SOFT™ Universal Reusable Patient Return Electrode & MEGA SOFT™ Universal Dual Reusable Patient Return Electrode* (Product code 0845 and 0846) [Instructions For Use]. Cincinnati (OH): MEGADYNE Medical Products, Inc., March 2025. https://www.e-ifu.com/
3. *MEGA SOFT™ Universal Plus Reusable Patient Return Electrode & MEGA SOFT™ Universal Plus Dual Reusable Patient Return Electrode* (Product code 0847 and 0848) [Instructions For Use]. Cincinnati (OH): MEGADYNE Medical Products, Inc., March 2025. https://www.e-ifu.com/
4. *Mega 2000™ and Mega Soft™ Patient Return Electrodes - Potential Risk of Patient Burn Injuries.* Health Canada, 2024. https://recalls-rappels.canada.ca/en/alert-recall/mega-2000tm-and-mega-softtm-patient-return-electrodes-potential-risk-patient-burn

Notice of market authorization with conditions

A Notice of Compliance with Conditions (NOC/c) is a form of market authorization with conditions granted to a product on the basis of promising evidence of clinical effectiveness following review of the submission by Health Canada. Communicating a NOC/c is intended to raise awareness on the details of the drug and the type of authorization granted.

Healthcare professionals are encouraged to report to Health Canada any adverse reactions suspected of being associated with marketed health products, including drugs authorized under the NOC/c policy.

The content of these notices reflects current information at the time of publication. Conditions associated with the NOC/c will remain until they have been fulfilled and authorized by Health Canada. For the most up-to-date information, consult Health Canada's NOC database.

Iqirvo (elafibranor): Authorization with conditions

Health Canada has issued a Notice of Compliance, under the Notice of Compliance with Conditions policy, for Iqirvo (elafibranor), oral tablets, 80mg. Iqirvo is indicated for the treatment of primary biliary cholangitis in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA. Patients should be advised of the conditional market authorization for this indication.

For the complete prescribing information and information available for patients/caregivers, please consult the Iqirvo Canadian product monograph. The product monograph can be accessed through Health Canada's Drug Product Database, the Ipsen website or by contacting Ipsen at 1-855-215-2288. Contact the company for a copy of any references, attachments or enclosures.

Helpful links

- 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
- COVID-19 vaccines and treatments portal

Contact us

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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