Health Canada | Santé Canada

Your health and safety… our priority. | *Votre santé et votre sécurité… notre priorité.*

Health Product InfoWatch

February 2020

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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

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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.

HEALTH PRODUCTS MENTIONED IN THIS ISSUE

Pharmaceuticals and Biologics
Mekinist (trametinib)
PMS-Nystatin Oral Suspension
Tafinlar (dabrafenib mesylate)
Tapazole (methimazole)

Other
Unauthorized health products

ANNOUNCEMENT

Mandatory reporting by hospitals guidance document

On December 16, 2019, new mandatory reporting requirements for hospitals came into force. Under the regulations, hospitals are now required to report to Health Canada all serious adverse drug reactions and medical device incidents within 30 days of being documented at the hospital.

Mandatory reporting of serious adverse drug reactions and medical device incidents by hospitals - Guidance document provides hospitals with information that may be useful in complying with the regulations. Comments on the guidance document are welcome and any comments received before March 31, 2020, will help to inform document revisions in advance of a formal guidance consultation planned for the fall of 2020.

To comment on the current guidance please contact the Canada Vigilance Program.
Email hc.canada.vigilance.sc@canada.ca
Phone: 1-866-234-2345 | Fax: 1-866-678-6789

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.

Health Product InfoWatch 2015 - 2020 5 years

Canada

MONTHLY RECAP OF HEALTH PRODUCT SAFETY INFORMATION

The following is a list of health product advisories, type I recalls as well as summaries of completed safety reviews published in January 2020 by Health Canada.

PMS-Nystatin Oral Suspension Advisory	Pharmascience Inc. recalled one lot of PMS-Nystatin Oral Suspension, because it may contain clumps or jelly-like material that may pose a choking risk. Newborns, infants and people with difficulty swallowing are particularly at risk.
Unauthorized health products Multiple unauthorized health products Unauthorized ZO Medical skin-whitening creams in North York, Ontario	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, in some cases, to stimulate reporting of similar adverse reactions.

PRODUCT MONOGRAPH UPDATES

The following safety labelling updates, which were recently made to the Canadian product monograph, 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. Canadian product monographs can be accessed through Health Canada's Drug Product Database.

Mekinist (trametinib) and Tafinlar (dabrafenib mesylate)

The risk of **severe cutaneous adverse reactions (SCARs)** has been included in the *Warnings and Precautions* and *Consumer Information* sections of the Canadian product monographs for Mekinist and Tafinlar.

Key messages for healthcare professionals:[1,2]

- Cases of SCARs, including Stevens-Johnson syndrome (SJS) and drug reaction with eosinophilia and systemic symptoms (DRESS), which can be life-threatening or fatal, have been reported during combination therapy with Mekinist and Tafinlar.
- Before initiating treatment, patients should be advised of the signs and symptoms of SCARs and monitored closely for skin reactions. If signs and symptoms suggestive of SCARs appear, Mekinist and Tafinlar should be withdrawn.

References

1. *Mekinist (trametinib)* [product monograph]. Dorval (QC): Novartis Pharmaceuticals Canada Inc.; 2019.
2. *Tafinlar (dabrafenib mesylate)* [product monograph]. Dorval (QC): Novartis Pharmaceuticals Canada Inc.; 2019.

Tapazole (methimazole)

The risk of **acute pancreatitis** has been included in the *Contraindications, Warnings and Precautions, Post-Market Adverse Drug Reactions* and *Consumer Information* sections of the Canadian product monograph for Tapazole.

Key messages for healthcare professionals:[1]

- Tapazole is now contraindicated in patients with a history of acute pancreatitis after administration of methimazole.
- There have been post-marketing reports of acute pancreatitis in patients receiving methimazole.
- In case of acute pancreatitis, Tapazole should be discontinued immediately. Tapazole treatment should not be started in patients with a history of acute pancreatitis that has been attributed to methimazole. Re-exposure may result in recurrence of acute pancreatitis with decreased time to onset.

References

1. *Tapazole (methimazole)* [product monograph]. Saint-Laurent (QC): Paladin Labs Inc.; 2019.

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 Register
- Drug Shortages Canada
- Annual trends for adverse reaction case reports and medical device problem incidents
- Stop Illegal Marketing of Drugs and Devices

Suggestions?

Your comments are important to us. Let us know what you think by reaching us at HC.infowatch-infovigilance.SC@canada.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.

ISSN: 2368-8025
Cat.: H167-1E-PDF
Pub.: 190000