Health Canada Santé Canada

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

# Health Product InfoWatch

February 2019

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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.

## HEALTH PRODUCTS MENTIONED IN THIS ISSUE

**Pharmaceuticals and Biologics**

Fibristal (ulipristal acetate)
Gilenya (fingolimod)
Hydrochlorothiazide
Idhifa (enasidenib)
Lartruvo (olaratumab)
Spinraza (nusinersen)
Sulfamethoxazole

**Other**

Unauthorized health products

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.

Canada

# ANNOUNCEMENT

## Update on Biologics Naming

Health Canada has released a policy statement on the naming of biologic drugs. The naming convention for biologic drugs, including biosimilars, will consist of a unique brand name and non-proprietary (common) name, without the addition of a product-specific suffix. Both brand name and non-proprietary name should be used throughout the medication use process. All biologic drugs will continue to have unique Drug Identification Numbers.

Health Canada thanks those who responded to the 2018 Consultation on the Naming of Biologic Drugs. A What We Heard Report summarizing the results of the consultation has also been published.

# 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 2019 by Health Canada.*

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| **Fibristal (ulipristal acetate)**<br>Information Update | Health Canada informed Canadians that its safety review of Fibristal (ulipristal acetate) found a possible link between its use and the risk of a rare but serious liver injury. Health Canada has worked with the manufacturer to update the Canadian product monograph for Fibristal to include new restrictions for use as well as requirements for liver function monitoring before, during and after treatment. |
| **Hydrochlorothiazide**<br>Health Product Infowatch<br>Information Update<br>Summary Safety Review | This safety review evaluated the risk of non-melanoma skin cancer (NMSC) associated with hydrochlorothiazide (HCTZ). Health Canada's review of the relevant evidence concluded that there is a potential risk of developing NMSC with prolonged use of HCTZ. However, uncertainty remains due to limitations noted in the reviewed studies. Patients taking HCTZ-containing products should be advised to regularly check their skin for new lesions as well as changes to existing lesions and report any suspicious skin lesions. Patients should be advised to practice routine sun-safety. Alternatives to HCTZ may be considered for patients who are at a particularly high risk for NMSC. Health Canada will work with the manufacturers to update the product monographs of all HCTZ-containing products. Health Canada also communicated this information to healthcare professionals and to the public. |
| **Lartruvo (olaratumab)**<br>Health Professional Risk Communication | The global, Phase III study (ANNOUNCE) of Lartruvo used in combination with doxorubicin did not confirm the clinical benefit in prolonging lives of patients with advanced or metastatic soft tissue sarcoma compared to doxorubicin alone. Based on the information available, no new safety concerns were identified during the study. Patients who currently are receiving Lartruvo should discuss with their physician whether to continue their course of therapy. Lartruvo should not be initiated in new patients outside of an investigational setting. |

| | |
|---|---|
| **Sulfamethoxazole-containing products**<br>Summary Safety Review | This safety review evaluated the risk of drug reaction with eosinophilia and systemic symptoms (DRESS) associated with sulfamethoxazole-containing products. Health Canada's review of the available information concluded that there is not enough evidence at this time to establish a link between the risk of DRESS and the use of sulfamethoxazole-containing products. Additionally, some of the signs and symptoms of DRESS are already included in the Canadian product monographs. For these reasons, Health Canada's review concluded that the safety information for these products is appropriate at this time. |
| **Unauthorized health products**<br>Advisories:<br>Panasilver<br>Products sold by A1 Herbal Ayurvedic Clinic Ltd. | 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 is available on Health Canada's Product Monograph Brand Safety Updates. Canadian product monographs can be accessed through Health Canada's Drug Product Database.*

### Gilenya (fingolimod)

The risk of **multiple sclerosis rebound (return of disease activity) after fingolimod discontinuation** has been included in the *Warnings and Precautions* section of the Canadian product monograph for Gilenya.

**Key messages for healthcare professionals:**[1]

- In the post-marketing setting, severe exacerbation of disease activity has been observed rarely in some patients stopping fingolimod.
- Healthcare professionals are advised to monitor patients for development of high disease activity following discontinuation of Gilenya and begin appropriate treatment as needed.

**Reference**

1. *Gilenya (fingolimod)* [product monograph]. Dorval (QC): Novartis Pharmaceuticals Canada Inc.; 2018.

## Spinraza (nusinersen)

The risk of **hydrocephalus** has been included in the *Warnings and Precautions* and *Patient Medication Information* sections of the Canadian product monograph for Spinraza.

### Key messages for healthcare professionals:[1]

- There have been reports of communicating hydrocephalus not related to meningitis or bleeding in patients treated with Spinraza in the post-market setting. A ventriculo-peritoneal shunt (VPS) was implanted in some patients to treat this condition.
- At present, the benefits and risks of Spinraza treatment in patients with VPS are unknown. The maintenance of treatment needs to be carefully considered.
- Physicians are advised to closely monitor patients with decreased consciousness and consider an evaluation for hydrocephalus.

**Reference**

1. *Spinraza (nusinersen)* [product monograph]. Mississauga (ON): Biogen Canada Inc.; 2018.

## 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 nature 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, in accordance with the NOC/c Policy. For the most up-to-date information, consult Health Canada's NOC database.*

## Idhifa (enasidenib): Authorization with conditions

Health Canada has issued a Notice of Compliance, under the Notice of Compliance with Conditions policy for Idhifa (enasidenib), 50 mg, 100 mg tablets for oral use. Idhifa is indicated for the treatment of adult patients with relapsed or refractory Acute Myeloid Leukemia (AML) with an isocitrate dehydrogenase-2 (IDH2) mutation. Patients should be advised about the conditional market authorization for this indication.

For the complete prescribing information and information available for the patients/caregivers, please consult the Idhifa Canadian product monograph. The product monograph can be accessed through Health Canada's Drug Product Database, the Celgene Inc. Web site or by contacting Celgene Inc. at 1-877-923-5436. Contact the company for a copy of any references, attachments or enclosures.

## HELPFUL LINKS

- MedEffect™ Canada
- Recalls and Safety Alerts Database
- New Safety 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

## Suggestions?

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

Health Canada
Marketed Health Products Directorate
Address Locator 1906C
Ottawa ON K1A 0K9
Telephone: 613-954-6522
Fax: 613-952-7738

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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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