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# Health Product InfoWatch

December 2020

## HEALTH PRODUCTS MENTIONED IN THIS ISSUE

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#### Pharmaceuticals and Biologics

- Bamlanivimab
- Pfizer-BioNTech COVID-19 Vaccine
- Prescription opioids
- Valcyte (valganciclovir)

#### Natural and Non-prescription Health Products

- Hand sanitizers that may pose health risks

#### Other

- Ultraviolet lights and wands
- Unauthorized health products

### 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](#).

## CORONAVIRUS DISEASE (COVID-19)

For the most up-to-date information on COVID-19, please visit the Government of Canada Coronavirus disease (COVID-19) website [Canada.ca/coronavirus](https://Canada.ca/coronavirus), which includes a dedicated section for [healthcare professionals](#) and for the [health product industry](#).

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

## DRUG AND VACCINE AUTHORIZATIONS FOR COVID-19

The *Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19* (the Interim Order) allows for the issuance of an expedited authorization for the importation, sale and advertising of drugs used in relation to COVID-19; this includes both human and veterinary drugs. The Interim Order introduces expedited authorization pathways for drugs with a COVID-19 indication that are not yet authorized in Canada or other jurisdictions; as well as COVID-19 drugs that are authorized for sale by a foreign regulatory authority. In addition, the Interim Order provides a mechanism to permit the sale of a drug that is already authorized in Canada under this Interim Order or the Food and Drug Regulations, for indications related to COVID-19 that are not included in the drug's authorization.

### **Bamlanivimab: Authorization with terms and conditions**

Health Canada has authorized with terms and conditions, under the Interim Order, bamlanivimab for injection, solution for infusion, 700 mg/20 mL (35 mg/mL) for use in relation to COVID-19, pending the results of trials to verify its clinical benefit. Patients should be advised of the nature of the authorization.

Bamlanivimab is a monoclonal antibody directed against the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spike protein. Bamlanivimab is indicated for the treatment of adults and pediatric patients 12 years of age or older with mild to moderate COVID-19 illness, who weigh at least 40 kg and who are at high risk of progressing to severe COVID-19 illness and/or hospitalization.

For the complete prescribing information and information available for patients/caregivers, please consult the bamlanivimab Canadian product monograph. The product monograph can be accessed through Health Canada's [Drug Product Database](#), at [www.lilly.ca](http://www.lilly.ca) or [www.bamlanivimabHCPinfo.com](http://www.bamlanivimabHCPinfo.com), or by contacting Eli Lilly Canada, Inc. at 1-888-545-5972. Contact the company for a copy of any references, attachments or enclosures.

[COVID-19 vaccines and treatments portal: Bamlanivimab \(bamlanivimab\)](#)

### **Pfizer-BioNTech COVID-19 Vaccine (COVID-19 mRNA Vaccine): Authorization with terms and conditions**

Health Canada has authorized with terms and conditions, under the Interim Order, Pfizer-BioNTech COVID-19 Vaccine (COVID-19 mRNA Vaccine), suspension for intramuscular injection, multiple dose vials (after dilution each vial contains 5 doses of 0.3 mL) for use in relation to COVID-19.

Pfizer-BioNTech COVID-19 Vaccine is indicated for active immunization to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.

For the complete prescribing information and information available for patients/caregivers, please consult the Pfizer-BioNTech COVID-19 Vaccine Canadian product monograph. The product monograph can be accessed through Health Canada's [Drug Product Database](#), the government's [covid-vaccine.canada.ca](http://covid-vaccine.canada.ca) website, at [www.pfizer.ca](http://www.pfizer.ca) or [CVDvaccine.ca](http://CVDvaccine.ca), or by contacting Pfizer Canada ULC at 1-800-463-6001. Contact the company for a copy of any references, attachments or enclosures.

[COVID-19 vaccines and treatments portal: Pfizer-BioNTech COVID-19 Vaccine](#)

## MONTHLY RECAP OF HEALTH PRODUCT SAFETY INFORMATION

The following is a list of [health product advisories](#), [type I recalls](#) and [summaries of completed safety reviews](#) published in November 2020 by Health Canada.

<p><b>Certain hand sanitizers that may pose health risks</b></p> <p><a href="#">Advisory</a></p>	<p>Health Canada advised Canadians that certain hand sanitizers were recalled because they either contain ingredients that are not permitted by Health Canada or are not properly labelled and are missing important information.</p>
<p><b>Ultraviolet lights and wands</b></p> <p><a href="#">Advisory</a></p>	<p>Health Canada advised Canadians about the risks of using ultraviolet (UV) lights and wands that make unproven claims to disinfect against the COVID-19 virus. This includes ultraviolet C (UVC) products. UVC is an extremely dangerous form of UV radiation and, although it can destroy some germs on non-porous surfaces, if used on the skin, there is a risk that it can cause harm or injury. Health Canada is aware of UV lights and wands being advertised for home use (e.g., for disinfecting cell phones, car keys and wallets) with claims that they can protect against COVID-19. Health Canada has not yet received any evidence to demonstrate that UV lights can protect specifically against COVID-19.</p>
<p><b>Unauthorized health products</b></p> <p><a href="#">Unauthorized nicotine buccal pouches</a></p> <p><a href="#">Unlicensed soft-shelled hyperbaric chambers</a></p> <p><a href="#">Various unauthorized health products</a></p>	<p>Health Canada advised Canadians about various unauthorized health products being sold at retail locations across Canada or online that may pose serious health risks.</p>

# 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.

## SAFETY BRIEF

### Opioid Safety Reminders

In 2018, Health Canada added requirements under the *Food and Drug Regulations* for warning stickers and patient information handouts to be provided with prescription opioids at the time of sale.<sup>1</sup> The [sticker](#) warns patients about the risks of dependence, addiction and overdose. The [patient information handout](#) contains broader information on the safe use of opioids as well as the risks associated with opioid use, including serious warnings, signs of overdose, possible side effects, and information on safe storage and disposal. Opioids administered under the supervision of a healthcare professional, such as in a hospital setting, as well as opioids authorized and used for the treatment of an opioid use disorder, are not required to have a warning sticker and patient information handout.

Based on the results of a recent survey, Health Canada would like to remind healthcare professionals to counsel patients about the following important safety and usage information contained in the patient information handout and to affix the warning stickers when required.

#### Information for Patients and Families:

##### Serious warnings

- **Opioid overdose can lead to death.** Overdose is more likely to happen at higher doses, or if you take opioids with alcohol or with other sedating drugs (such as sleeping pills, anxiety medication, anti-depressants, muscle relaxants). Talk to a healthcare professional about whether any of the other medications you are taking may increase your risk.
- **Addiction** may occur, even when opioids are used as prescribed.
- **Physical dependence** can occur when opioids are used every day. This can make it hard to stop using them.
- **Life-threatening breathing problems or reduced blood pressure** may occur with opioid use. Talk to the health professional who prescribed your opioid about whether any health conditions you have may increase your risk.
- **Your pain may worsen** with long-term opioid use or at higher doses. You may not feel pain relief with further increases in your dose. Talk to the health professional who prescribed your opioid if this happens to you, as a lower dose or change in treatment may be required.
- **Withdrawal symptoms** such as widespread pain, irritability, agitation, flu-like symptoms and trouble sleeping, are common when you stop or reduce the use of opioids.
- **Babies born to mothers taking opioids** may develop life-threatening withdrawal symptoms.
- **Use only as directed.** Crushing, cutting, breaking, chewing or dissolving some types of opioids before consuming them can cause serious harm, including death.

### Signs of overdose

- hallucinations
- confusion
- difficulty walking
- extreme drowsiness/dizziness
- slow or unusual breathing
- unable to be woken up
- cold and clammy skin

### Possible side effects

- reduced physical and or/mental abilities, depression
- drowsiness, dizziness, risks of falls/fractures
- heart palpitations, irregular heartbeat
- problems sleeping, may cause or worsen sleep apnea
- vision problems, headache
- low sex drive, erectile dysfunction, infertility
- severe constipation, nausea, vomiting

### Your opioids may be fatal to others

- **Never give your opioid medicine to anyone.**
- Store opioids (including used patches) in a secure place to prevent theft, problematic use or accidental exposure.
- Keep opioids out of sight and reach of children and pets. Taking even one dose by accident can be fatal.
- Never throw opioids (including used patches) into household trash where children and pets may find them.
- Return expired, unused or used opioids (including patches) to a pharmacy for proper disposal.

Health Canada would like to remind all healthcare professionals that the availability of naloxone kits should be regularly discussed with patients and that a prescription may not be needed.

Healthcare professionals are also encouraged to [report to Health Canada](#) any adverse reaction suspected of being associated with the use of opioid medications.

For further information on the requirements please see:

[Health Canada's Questions and Answers: Prescription Opioids – Sticker and Handout Requirements for Pharmacists and Practitioners](#)

For access to a printable version, please see the [Patient Information Handout](#).

#### Reference

1. Part C Drugs. *Food and Drug Regulations*, 2020; C.01.005.1

## 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](#) page. Canadian product monographs can be accessed through Health Canada's [Drug Product Database](#).

### Valcyte (valganciclovir)

The *Dosage and Administration* and *Consumer Information* (powder for oral solution) sections of the Canadian product monograph for Valcyte have been updated to include information related to the **change in graduation on the oral dosing dispenser** from milligrams (mg) to millilitres (mL).

#### Key messages for healthcare professionals:<sup>1</sup>

- Valcyte (valganciclovir) powder for oral solution, 50 mg/mL when reconstituted, has a new oral dosing dispenser. The oral dosing dispenser is now graduated in mL. A 50 mg dose is equivalent to 1 mL.
- Healthcare professionals are advised to calculate the valganciclovir dose in mg and use the conversion table, which is available in the product monograph, to administer the correct dose of Valcyte oral solution in mL.

Valganciclovir dose	Valcyte oral solution to be administered
50 mg	1 mL
75 mg	1.5 mL
100 mg	2 mL
500 mg	10 mL

- Healthcare professionals should also review information concerning the new oral dosing dispenser and its markings with patients.

#### Reference

1. *Valcyte (valganciclovir)* [product monograph]. Mississauga (ON): Hoffmann-La Roche Limited; 2020.

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## 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](#)
- [Stop Illegal Marketing of Drugs and Devices](#)
- [List of Drugs for Exceptional Importation and Sale](#)
- [Drug and vaccine authorizations for COVID-19: List of authorized drugs, vaccines and expanded indications](#)

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## Suggestions?

Your comments are important to us. Let us know what you think by reaching us at [HC.infowatch-infovigilance.SC@canada.ca](mailto: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.*

ISSN: 2368-8025  
Cat.: H167-1E-PDF  
Pub.: 200000

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