

Importation of United Kingdom-labelled Glyceryl Trinitrate (Nitroglycerin) 0.4 mg/dose Sublingual Metered Dose Spray due to shortage of Canadian-authorized nitroglycerin sublingual sprays

Due to the shortages of nitroglycerin sprays in Canada, Health Canada has allowed the temporary importation of Juno Pharmaceuticals Inc. UK-labelled Nitroglycerin 0.4 mg/dose Metered Dose Spray with English labels. This medication has been added to Health Canada's List of Drugs for Exceptional Importation and Sale in Canada.

A Temporary Product Identification Number has been assigned to this **(UK) Nitrolingual Pumpspray 0.4 mg/dose Metered Dose Spray (PIN 9858317)** with an effective as of **December 4, 2023**. **Note, supply is estimated to be available for purchase the week of December 4, 2023.**

Pharmacists should advise patients of the differences between the UK-authorized product and Canadian-marketed products highlighted above and that the UK-authorized drug product should be primed, administered and stored in the same manner as the Canadian-marketed products.

In Canada, nitroglycerin sublingual spray is indicated for the management and treatment of acute attacks of angina pectoris.

The UK-authorized drug product and Canadian-marketed nitroglycerin sublingual spray drug products have the **same active ingredient, strength (0.4 mg per metered dose) and route of administration**; however, **the products differ in the following ways**:

- **Nomenclature used for the active ingredient:** "Glyceryl trinitrate" is used in the UK product labelling whereas "Nitroglycerin" is used in the labelling of the Canadian-marketed products.
- **Product composition:** The Canadian-marketed products are aromatized oily solutions containing peppermint oil as a flavouring agent while the **UK-authorized product does not contain peppermint oil and thus does not have the same peppermint aroma.**
 - The **UK-authorized product contains propylene glycol as an excipient**, which is not present in the Canadian-marketed products. **Due to its propylene glycol content, the UK-authorized product can cause skin irritation.**
 - **Number of metered doses in each container:** The UK-authorized drug product contains **180 metered doses** while the Canadian-marketed products contain 200 metered doses.
- **Expression of strength:** The UK-authorized products states "400 mcg per metered dose" whereas the Canadian format for expressing the equivalent strength is "0.4 mg per metered dose."

Information about the UK-authorized Glyceryl Trinitrate Sublingual Spray for healthcare professionals is available for reference in English only at the following link: <https://www.medicines.org.uk/emc/product/11759/smpc>

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PHARMACY BENEFACT

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Please consult the reference for more information on the following:

- indications
- contraindications
- warnings and precautions
- adverse reactions
- drug interactions
- dosage and administration (including priming instructions)
- storage and stability
- handling instructions

Health care professionals are reminded that concomitant use of Nitroglycerin (or Glyceryl Trinitrate) Sublingual Spray and sildenafil, tadalafil, vardenafil or any other cGMP-specific phosphodiesterase Type 5 inhibitor could result in life-threatening hypotension with syncope or myocardial infarction and death.

Reporting adverse drug reactions

Adverse drug reactions associated with the use of UK-authorized Glyceryl Trinitrate Sublingual Spray should be reported to Juno Pharmaceuticals Corp. by calling 1-855-819-0505 or 1-866-663-1747 AND to Health Canada at <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html> or by calling toll-free at 1-866-234-2345.

Temporary benefit added to the *Alberta Drug Benefit List (ADBL)*

To ensure coverage is provided for this product, for members of eligible government-sponsored drug programs, **(UK) Nitroglycerin 0.4 mg/Dose Metered Dose Spray (PIN 9858317)** will be considered a temporary benefit for the Alberta Drug Benefit List (ADBL).

As of **December 4, 2023**, all claims for this product will be adjudicated to the price of **\$0.0468 per dose**.

Alberta Blue Cross® will continue to monitor the availability of shorted product(s) and potential alternatives, in addition to working with other provinces and territories, manufacturers and Health Canada, to address this shortage and minimize the impact on Albertans.

For assistance with benefit or claim inquiries, please contact an Alberta Blue Cross Pharmacy Services Provider Relations contact centre representative at

780-498-8370 (Edmonton and area)
403-294-4041 (Calgary and area)
1-800-361-9632 (toll free)
FAX 780-498-8406 (Edmonton and area)
FAX 1-877-305-9911 (toll free)

Alberta Blue Cross offers online access to current Pharmacy Benefacts and supplemental claiming information to assist with the submission of your direct bill drug claims.

Visit ab.bluecross.ca/providers/pharmacy-home.php

