

Exceptional Importation of UK-Authorized Glyceryl Trinitrate (Nitroglycerin) Sublingual Spray Due to the Current Shortage of Canadian-Authorized Nitroglycerin Sublingual Spray

Juno Pharmaceuticals Corp.
402-2233 Argentia Road,
Mississauga, Ontario, Canada
L5N 2X7

November 17, 2023

Dear hospitals, wholesalers, pharmacists and healthcare professional associations:

There is a critical shortage of Nitroglycerin (otherwise known as glyceryl trinitrate) Sublingual Spray in Canada.

In order to help mitigate the shortage, Health Canada has permitted the exceptional, temporary importation and sale of UK-authorized Glyceryl Trinitrate Sublingual Spray, with English only labels, by Juno Pharmaceuticals Corp., and has added this product to the List of Drugs for Exceptional Importation and Sale (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-shortages/list.html>).

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”.

The UK-authorized Glyceryl Trinitrate Sublingual Spray can be used for the same indications as Canadian-marketed Nitroglycerin Sublingual Spray drug products.

Healthcare professionals should refer to the Canadian Product Monograph for Nitroglycerin Sublingual Spray (0.4 mg per metered dose) products available in English and French on the Health Canada Drug Product Database (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>) for information on the appropriate use of the UK-authorized product, including the:

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

Healthcare 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.

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.

Pharmacists should also inform patients that the UK-authorized product contains a **significant percentage of alcohol (ethanol)** which is flammable and explosive. Similar to the Canadian-marketed products, the UK-authorized product should **not** be stored or used near an open flame or source of heat or while smoking or near someone that is smoking. The canister should **not** be burned or pierced after use.

Information on the imported product

Brand name	Dosage form, strength and route of administration	Product packaging	Country of authorization and identifying code	Authorization holder	DEL holder/ Importer in Canada
Glyceryl Trinitrate Sublingual Spray	Non-aqueous solution, 400 mcg glyceryl trinitrate per metered dose, sublingual	Aluminum canister with a metered dosing valve and nozzle. Plastic protective cap. Each 180 doses canister contains 10 grams of solution.	United Kingdom PL 18190/0013	Egis Pharmaceuticals UK Ltd., United Kingdom <u>Distributed by:</u> Aspire Pharma Ltd. Petersfield, Hants GU32 3QG, UK	Juno Pharmaceuticals Corp., Canada

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>

Images of the UK-authorized product can be found in the appendix below. Healthcare professionals are advised that there may be other aspects of the inner and outer labels and packaging of the UK-authorized drug product that differ from marketed Nitroglycerin Sublingual Spray products in Canada. **Proper selection of the intended drug product must be verified to avoid confusion with other drug products and prevent medication errors.**

The UK-authorized product does not have a drug identification number (DIN) or a barcode that scans in medication management systems in Canada. A facility-generated sticker may be required to enable barcode scanning and allow the product being dispensed and administered to be properly identified.

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 or 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.

Questions or concerns

For questions or concerns about UK-authorized Glyceryl Trinitrate Sublingual Spray, please contact

Juno Pharmaceuticals Corp., 402-2233 Argentia Road, Mississauga, ON, L5N 2X7.

Appendices

1. Images of UK-authorized Glyceryl Trinitrate Sublingual Spray

Sincerely,

Paul J. Varady
VP, Quality and Regulatory Affairs
Juno Pharmaceuticals Canada

Appendix 1 - Images of UK-authorized Glyceryl Trinitrate Sublingual Spray

Product Photo



UK Canister Label

<p>Glyceryl Trinitrate 400 micrograms /metered dose, sublingual spray</p> <p>Each metered dose contains 400 micrograms of glyceryl trinitrate. Also contains: ethanol, propylene glycol in a CFC-free pump spray. For sublingual use. pump spray 180 doses</p> <p>MA holder: EGIS Pharmaceuticals UK Ltd.</p>	<p>Use as directed by the doctor. Read the package leaflet before use. Store below 25°C, in the original package in order to protect from light and radiant heat. Protect from sunlight and do not expose to temperatures above 50°C. Do not use it near to anyone that is smoking; or spray the product into a naked flame or onto a hot surface. Do not pierce or burn the canister after use. For Batch No and Expiry date see base of bottle. Keep out of the sight and reach of children. Avoid breathing in the spray.</p>	<p>PL18190/0013 1010029-L8.6 P</p>  <p>Distributed by: Aspire Pharma Ltd Petersfield, Hants GU32 3QG, UK</p>
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Plain text UK canister label

<p>LEFT PANEL</p>
<p>In orange text: Glyceryl Trinitrate In light blue text: 400 micrograms /metered dose, sublingual spray Each metered dose contains 400 micrograms of glyceryl trinitrate. Also contains: ethanol, Propylene glycol in a CFC-free pump spray. For sublingual use. pump spray In orange text: 180 doses MA holder: EGIS Pharmaceuticals UK Ltd.</p>
<p>RIGHT PANEL</p>
<p>Use as directed by the doctor. Read the package leaflet before use. Store below 25°C, in the original package in order to protect from light radiant heat. Protect from sunlight and do not expose to temperatures above 50°C. Do not use it near to anyone that is smoking; or spray the product into a</p>

naked flame or onto a hot surface.

Do not pierce or burn the canister after use.

For Batch No and Expiry date see base of bottle

Keep out of the sight and reach of children.

Avoid breathing in the spray.

Barcode 6237604G

Aspire Pharma corporate logo

Distributed by:

Aspire Pharma Ltd

Petersfield, Hants

GU323QG, UK

Right margin text in a Box: **P**

Additional right margin vertically oriented text: PL18190/0013 1010029-L8.6

UK Carton Label

Front, Back and Side Panels

Each metered dose contains **400 micrograms of glyceryl trinitrate.**

Also contains: ethanol, propylene glycol and a particle-free solution in a **CFC-free pump spray.**

For sublingual use.

Read the package leaflet before use.

Use as directed by the doctor.

Store below 25°C, in the original package in order to protect from light and radiant heat.


Protect from sunlight and do not expose to temperatures above 50°C.

Do not use it near to anyone that is smoking; or spray the product into a naked flame or onto a hot surface.

Do not pierce or burn the canister after use.

Keep out of the sight and reach of children.

Avoid breathing in the spray.



Glyceryl Trinitrate sublingual spray

400 mcg/metered dose


MA holder:
EGIS Pharmaceuticals UK Ltd.
127 Shirland Road
London W9 2EP

Distributed by:
Aspire Pharma Ltd
Unit 4
Rotherbrook Court
Bedford Road
Petersfield
Hampshire
GU32 3QG
United Kingdom

P

PL 18190/0013

180 doses




Glyceryl Trinitrate sublingual spray


400 mcg/metered dose

pump spray

180 doses

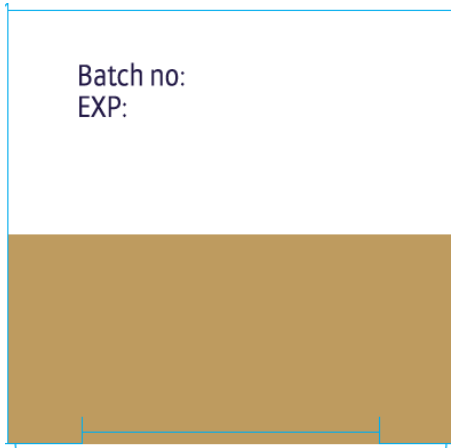


Affix Glyceryl Trinitrate 400 micrograms/metered dose, sublingual spray pharmacy label here



5 060209 730004

Top Panel



Bottom Panel



Plain text UK carton label

BACK PANEL

Each metered dose contains **400 micrograms of glyceryl trinitrate**.

Also contains: Ethanol, propylene glycol and a particle-free solution in a **CFC-free pump spray**.

For sublingual use.

Read the package leaflet before use.

Use as directed by the doctor.

Store below 25°C, in the original package in order to protect from light and radiant heat.

Protect from sunlight and do not expose to temperatures above 50°C.

Do not use it near to anyone that is smoking; or spray the product into a naked flame or onto a hot surface.

Do not pierce or burn the canister after use.

Keep out of the sight and reach of children. Avoid breathing in the spray.

ASPIRE PHARMA corporate logo

LEFT PANEL

In orange text: Glyceryl Trinitrate

In a circle to the right of the text: 400 mcg/metered dose **sublingual spray**

MA holder:

EGIS Pharmaceuticals

UK Ltd.

127 Shirland Road

London W9 2EP

Distributed by:

Aspire Pharma Ltd

Unit 4

Rotherbrook Court

Bedford Road

Petersfield

Hampshire

GU32 3QG

United Kingdom

In a box: **P**

PL 18190/0013

In orange text: 180 doses

MAIN PANEL

In orange text: Glyceryl Trinitrate

In a circle to the right of the text: 400 mcg/metered dose

Sublingual spray

pump spray

In orange text: 180 doses

RIGHT PANEL

Affix Glyceryl Trinitrate 400 micrograms/metered dose, sublingual spray pharmacy label here

Barcode 50602097330004

TOP PANEL

Batch no:

EXP:

BOTTOM PANEL

In orange text: Glyceryl Trinitrate

In a circle to the right of the text: 400 mcg/metered dose

Sublingual spray

In orange text: 180 doses

ASPIRE PHARMA corporate logo

BRAILLE TEXT ON PRODUCT CARTON

Glyceryl

trinitrate

#400 mcg/

metered dose

sublingual

spray