

Exceptional Importation of UK-Authorized Eptifibatide Injection 0.75 mg/mL and 2 mg/mL Vials Due to the Current Shortage of Canadian-Authorized Eptifibatide Injection 0.75 mg/mL and 2 mg/mL

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

March 9, 2023

Dear hospitals, wholesalers, pharmacists and healthcare professional associations:

There is a critical shortage of eptifibatide injection (0.75 mg/mL and 2 mg/mL) in Canada.

In order to help mitigate the shortage, Health Canada has permitted the exceptional, temporary importation and sale of Kensington Pharma's UK-authorized Eptifibatide 0.75 mg/mL Solution for Infusion and Eptifibatide 2 mg/mL Solution for Injection, 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, eptifibatide injection is indicated for:

- the treatment of patients presenting with symptoms of unstable angina (UA)/non-ST-segment elevation myocardial infarction (NSTEMI), including those patients who may subsequently undergo percutaneous coronary intervention (PCI) as well as those who will be managed medically.
- the treatment of patients undergoing PCI including those undergoing intracoronary stenting.

Kensington Pharma's UK-authorized Eptifibatide 0.75 mg/mL Solution for Infusion and Eptifibatide 2 mg/mL Solution for Injection have the **same active ingredient, strengths, dosage form, route of administration and volumes (100 mL vial for 0.75 mg/mL strength and 10 mL vial for 2 mg/mL strength)** as Canadian-authorized products. However, the drug products **differ in their brand name**.

Kensington Pharma's UK-authorized Eptifibatide 0.75 mg/mL Solution for Infusion and Eptifibatide 2 mg/mL Solution for Injection can be used for the same indications as Canadian-authorized eptifibatide injection (0.75 mg/mL and 2 mg/mL). These Canadian Product Monographs are available in English and French on the Health Canada Drug Product Database (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>).

The Canadian Product Monographs on the database contains information on the appropriate use of the product, including the:

- indications
- contraindications
- warnings and precautions
- adverse reactions
- dosage and administration
- storage

Storage

Kensington Pharma's UK-authorized Eptifibatide 0.75 mg/mL Solution for Infusion and Eptifibatide 2 mg/mL Solution for Injection vials should be stored refrigerated at 2-8°C. Vials may be transferred to controlled room temperature storage (25°C with excursions permitted between 15-30°C) protected from light, for a period not to exceed 2 months. Upon transfer, vials must be marked with a "DISCARD BY" date (2 months from the transfer date), which may not exceed the labeled expiration date.

Information on the imported product

Brand name	Dosage form, strength and route of administration	Product description and packaging	Country of authorization and identifying code	Authorization holder	DEL holder/ Importer in Canada
Eptifibatide 2 mg/mL Solution for Injection	Solution, 2 mg/mL, for intravenous injection	Preservative-free Solution in a single dose 10 mL clear glass vial with a rubber stopper with an aluminum and blue plastic flip-off overseal.	United Kingdom PL 44853/0003	Kensington Pharma, United Kingdom	Juno Pharmaceuticals Corp., Canada
Eptifibatide 0.75 mg/mL Solution for Infusion	Solution, 0.75 mg/mL, for intravenous infusion	Preservative-free Solution in a single dose 100 mL clear glass vial with a rubber stopper with an aluminum and red plastic flip-off overseal.	United Kingdom PL 44853/0002	Kensington Pharma, United Kingdom	Juno Pharmaceuticals Corp., Canada

Information about UK-authorized Eptifibatide 0.75 mg/mL Solution for Infusion and Eptifibatide 2 mg/mL Solution for Injection for healthcare professionals is available for reference in English at the links provide.

0.75 mg /mL Solution for Infusion:

<http://kensingtonpharma.com/wp-content/uploads/2019/10/eptifibatide-SmPC-0.75mg.pdf>

2 mg/mL Solutions for Injection:

<http://kensingtonpharma.com/wp-content/uploads/2019/10/eptifibatide-SmPC-2mg.pdf>

Images of the UK-authorized product can be found in the Appendices below. Healthcare professionals are advised that aspects of the inner and outer labels and packaging of the UK-authorized drug product differ from authorized eptifibatide injection (0.75 mg/mL and 2 mg/mL) 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 Eptifibatide Injection 0.75 mg/1 mL and 2 mg/1 mL 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 Eptifibatide Injection 0.75 mg/1 mL and 2 mg/1 mL, please contact Juno Pharmaceuticals Corp., 402-2233 Argentia Road, Mississauga, ON, L5N 2X7.

Appendices

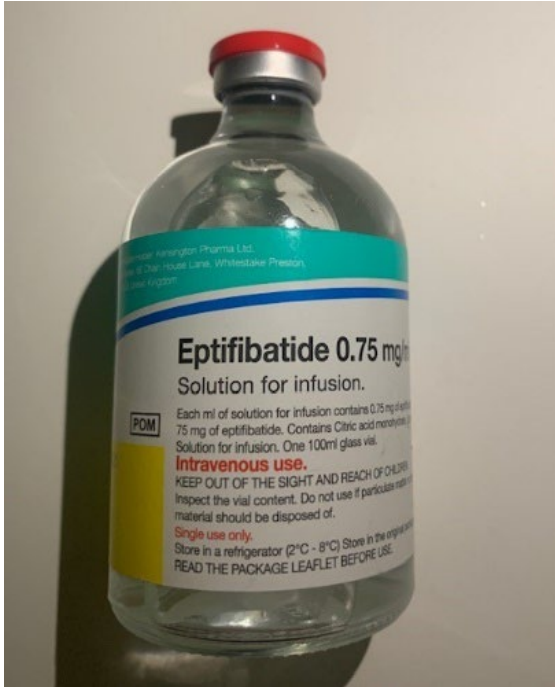
1. Images of UK-authorized Eptifibatide Injection 0.75 mg/1 mL
2. Images of UK-authorized Eptifibatide Injection 2 mg/1 mL

Sincerely,


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

Appendix 1 - Images of UK-Authorized Eptifibatide Injection 0.75 mg/1 mL

Product Photos



Bottle Label

		<p>Marketing Authorisation Holder: Kensington Pharma Ltd. Unit A Newlands House, 60 Chain House Lane, Whitestake Preston, Lancashire, PR4 4LG, United Kingdom</p>	<div style="border: 2px solid blue; border-radius: 50%; width: 60px; height: 60px; display: flex; align-items: center; justify-content: center; margin: 0 auto;"> <div style="text-align: center;"> <p>0.75 mg/ml</p> </div> </div>
<div style="border: 1px solid black; padding: 5px; width: fit-content;"> POM </div>		<p>Eptifibatide 0.75 mg/ml Solution for infusion.</p>	
<p>LOT: EXP:</p>		<p>Each ml of solution for infusion contains 0.75 mg of eptifibatide. One 100 ml vial contains 75 mg of eptifibatide. Contains Citric acid monohydrate, Sodium hydroxide and Water for injections. Solution for infusion. One 100ml glass vial.</p>	
<p>PL 44853/0002</p>		<p>Intravenous use. KEEP OUT OF THE SIGHT AND REACH OF CHILDREN. Inspect the vial content. Do not use if particulate matter or discolouration is present. Any unused material should be disposed of. Single use only. Store in a refrigerator (2°C - 8°C) Store in the original package in order to protect from light. READ THE PACKAGE LEAFLET BEFORE USE.</p>	

Plain text bottle label

MAIN PANEL	
Eptifibatide 0.75 mg/ml Solution for infusion.	0.75 mg/mL
<p>Each ml of solution for infusion contains 0.75 mg of eptifibatide. One 100 ml vial contains 75 mg of eptifibatide. Contains Citric acid monohydrate, Sodium hydroxide and Water for injections. Solution for infusion. One 100ml glass vial.</p> <p>Intravenous use.</p> <p>KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.</p> <p>Inspect the vial content. Do not use if particulate matter or discolouration is present. Any unused material should be disposed of.</p> <p>Single use only.</p> <p>Store in a refrigerator (2°C - 8°C) Store in the original package in order to protect from light.</p> <p>READ THE PACKAGE LEAFLET BEFORE USE.</p>	
SIDE PANEL	
<p>(logo) Kensington Pharma</p> <p>Marketing Authorisation Holder: Kensington Pharma Ltd.</p> <p>Unit A Newlands House, 60 Chain House Lane, Whitestake Preston, Lancashire, PR4 4LG, United Kingdom</p>	

Carton Label

Eptifibatide 0.75 mg/ml Solution for infusion.		Eptifibatide 0.75 mg/ml Solution for infusion.		Eptifibatide 0.75 mg/ml Solution for infusion.	
<p>Marketing Authorisation Holder: Kensington Pharma Ltd. Unit A Newlands House, 60 Chain House Lane, Whitestake Preston, Lancashire, PR4 4LG United Kingdom</p> <p>PL 44853/0002</p>  <p>5 060467 000208 ></p> <p>POM</p>		<p>0.75 mg/ml</p> <p>Eptifibatide 0.75 mg/ml Solution for infusion. One 100ml glass vial</p>		<p>0.75 mg/ml</p> <p>Eptifibatide 0.75 mg/ml Solution for infusion. One 100ml glass vial</p>	
		<p>Each ml of solution for infusion contains 0.75 mg of eptifibatide. One 100 ml vial contains 75 mg of eptifibatide. Contains Citric acid monohydrate, Sodium hydroxide and Water for injections.</p> <p>Intravenous use.</p> <p>KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.</p> <p>Inspect the vial content. Do not use if particulate matter or discolouration is present.</p> <p>Single use only.</p> <p>Store in a refrigerator (2°C - 8°C) Store in the original package in order to protect from light.</p> <p>Any unused material should be disposed of.</p> <p>READ THE PACKAGE LEAFLET BEFORE USE.</p>			
		<p>1 vial</p>		<p>1 vial</p>	

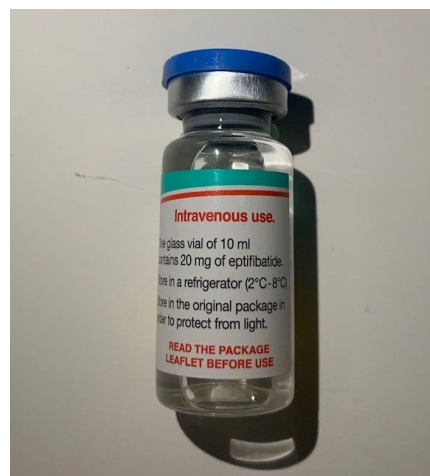
Plain text carton label

MAIN FRONT PANEL

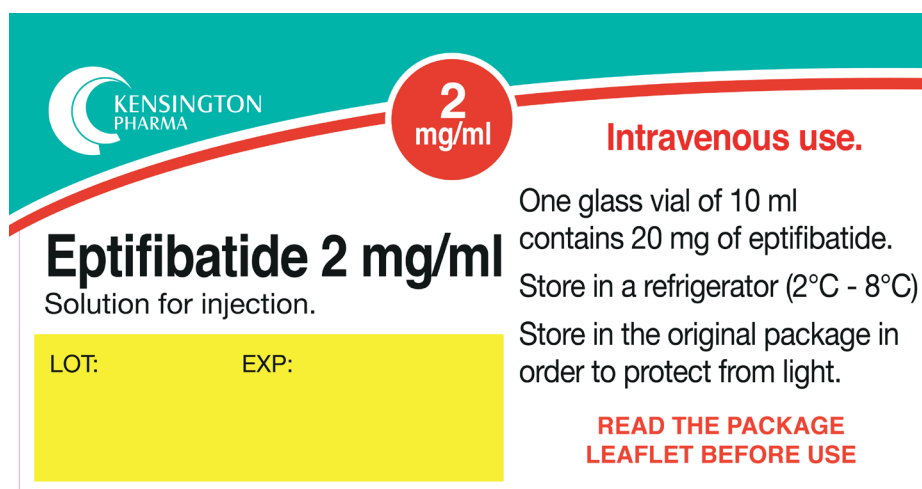
<p>(logo) Kensington Pharma</p> <p>Eptifibatide 0.75 mg/ml Solution for infusion. One 100ml glass vial 1 vial</p>	<p>0.75 mg/mL</p>
MAIN BACK PANEL	
<p>(logo) Kensington Pharma</p> <p>0.75 mg/mL</p> <p>Eptifibatide 0.75 mg/ml Solution for infusion. One 100ml glass vial</p>	<p>1 vial</p>
SIDE PANEL	
<p>Eptifibatide 0.75 mg/ml Solution for infusion.</p> <p>0.75 mg/mL</p> <p>Each ml of solution for infusion contains 0.75 mg of eptifibatide. One 100 ml vial contains 75 mg of eptifibatide. Contains Citric acid monohydrate, Sodium hydroxide and Water for injections. Intravenous use. KEEP OUT OF THE SIGHT AND REACH OF CHILDREN. Inspect the vial content. Do not use if particulate matter or discolouration is present. Single use only. Store in a refrigerator (2°C - 8°C) Store in the original package in order to protect from light. Any unused material should be disposed of. READ THE PACKAGE LEAFLET BEFORE USE.</p>	
SIDE PANEL	
<p>Eptifibatide 0.75 mg/ml Solution for infusion. Marketing Authorisation Holder: Kensington Pharma Ltd. Unit A Newlands House, 60 Chain House Lane, Whitestake Preston, Lancashire, PR4 4LG United Kingdom</p>	



Appendix 2 - Images of UK-Authorized Eptifibatide Injection 2 mg/1 mL



Bottle Label



Plain text bottle label

MAIN PANEL	
(logo) Kensington Pharma	2 mg/ml
Eptifibatide 2 mg/ml Solution for infusion.	
Lot:	Exp:
SIDE PANEL	
Intravenous use. One glass vial of 10 ml contains 20 mg of eptifibatide. Store in a refrigerator (2°C - 8°C) Store in the original package in order to protect from light.	

Carton Label

Eptifibatide 2 mg/ml
Solution for injection.

Eptifibatide 2 mg/ml
Solution for injection.

Tamper Evident

2 mg/ml

2 mg/ml

2 mg/ml

Marketing Authorisation Holder:
Kensington Pharma Ltd.

Unit A Newlands House,
60 Chain House Lane,
Whitestake Preston,
Lancashire,
PR4 4JG
United Kingdom

PL 44853/0003

5 060467 000192

1 vial

POM

Each ml of solution for injection contains 2 mg of eptifibatide.
One 10 ml vial contains 20 mg of eptifibatide.
Contains Citric acid monohydrate, Sodium hydroxide and Water for injections.

Intravenous use.
KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.
Inspect the vial content. Do not use if particulate matter or discolouration is present.
Single use only.
Store in a refrigerator (2°C - 8°C).
Store in the original package in order to protect from light.


Tamper Evident

1 vial

Any unused material :
READ THE PACKAGE
USE.

Plain text carton label

MAIN FRONT PANEL	
(logo) Kensington Pharma	2 mg/mL
Eptifibatide 2 mg/ml Solution for infusion. One 10 ml glass vial	
	1 vial

MAIN BACK PANEL	
<p>(logo) Kensington Pharma</p> <p style="text-align: center;">2 mg/mL</p> <p>Eptifibatide 2 mg/ml Solution for infusion. One 10 ml glass vial</p> <p style="text-align: right;">1 vial</p>	
SIDE PANEL	
<p>Eptifibatide 2 mg/ml Solution for infusion.</p> <p style="text-align: center;">2 mg/mL</p> <p>Each ml of solution for injection contains 2 mg of eptifibatide. One 10 ml vial contains 20 mg of eptifibatide. Contains Citric acid monohydrate, Sodium hydroxide and Water for injections. Intravenous use. KEEP OUT OF THE SIGHT AND REACH OF CHILDREN. Inspect the vial content. Do not use if particulate matter or discolouration is present. Single use only. Store in a refrigerator (2°C - 8°C). Store in the original package in order to protect from light. Any unused material should be disposed of. READ THE PACKAGE LEAFLET BEFORE USE.</p>	
SIDE PANEL	
<p>Eptifibatide 2 mg/ml Solution for infusion. Marketing Authorisation Holder: Kensington Pharma Ltd. Unit A Newlands House, 60 Chain House Lane, Whitestake Preston, Lancashire, PR4 4LG United Kingdom</p> <p style="text-align: center;">PL 44853/0003</p> <p style="text-align: center;">  5 060467 000192 > </p> <p style="text-align: center;">POM</p>	