

Exceptional Importation of UK-Authorized Ketamine Injection 50 mg/mL in 10 mL Vials Due to the Current Shortage of Canadian-Authorized Ketamine Injection

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

April 27, 2023

Dear hospitals, wholesalers, pharmacists and healthcare professional associations:

There is a critical shortage of ketamine injection in Canada.

In order to help mitigate the shortage, Health Canada has permitted the exceptional, temporary importation and sale of Hameln Pharma's UK-authorized Ketamine 50 mg/mL 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, ketamine injection is indicated for:

- As the sole anesthetic agent for recommended diagnostic and surgical procedures. Although best suited to short procedures, ketamine injection can be used, with additional doses, for longer procedures. **NOTE:** If skeletal muscle relaxation is desired, a muscle relaxant should be used. In surgical procedures involving visceral pain pathways, ketamine injection should be supplemented with an agent that obtunds visceral pain.
- For the induction of anesthesia prior to the administration of other general anesthetic agents.
- To supplement low potency agents such as nitrous oxide.

Specific areas of application or types of procedures have included:

- Neurodiagnostic procedures such as pneumoencephalograms, ventriculograms, myelograms, and lumbar punctures.
- Diagnostic and operative procedures of the eye, ear, nose and mouth. Eye movements may persist during ophthalmological procedures. Before Ketamine Injection can be recommended for intraocular surgery, more data are required.
- Diagnostic and operative procedures of the pharynx, larynx or bronchial tree. **NOTE:** Adequate muscle relaxants must be used in such procedures.

- Sigmoidoscopy and minor surgery of the anus and rectum, and circumcision.
- Extraperitoneal procedures used in gynecology such as dilation and curettage. More data is required before Ketamine Injection can be recommended for use in obstetrical delivery or caesarean section.
- Orthopedic procedures such as closed reductions, manipulations, femoral pinning, amputations, and biopsies.
- Dental extractions.
- Miscellaneous procedures of general surgery such as debridement, painful dressings, and skin grafting in burn patients.
- Anesthesia in poor-risk patients where depression of vital functions precludes the use of other general anesthetics.
- In procedures where the intramuscular route of administration is preferred.

The UK-authorized Ketamine 50 mg/mL Injection is available in 10 mL clear glass vials and contains ketamine hydrochloride (equivalent to 50 mg/mL ketamine base), benzethonium chloride (preservative) and water.

The UK-authorized product has the **same active ingredient, strength, excipients, dosage form, and routes of administration** as Canadian marketed ketamine injection (50 mg/mL) products.

The UK-authorized Ketamine 50 mg/mL Injection can be used for the same indications as Canadian marketed ketamine injection (50 mg/mL) products. Healthcare professionals should refer to the Canadian Product Monographs 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 contain information on the appropriate use of the product, including the:

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

Storage

The UK-authorized Ketamine 50 mg/mL Injection should be stored at 15-30°C and protected from light.

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
Ketamine 50 mg/mL Injection	Solution, 50 mg/mL, for intramuscular or intravenous injection	10 mL clear glass vial with a rubber stopper and an aluminum and white plastic flip-off overseal. Available in carton packs of 10 vials.	United Kingdom PL 01502/0099	Hameln Pharma Ltd., United Kingdom	Juno Pharmaceuticals Corp., Canada

Information about the UK-authorized Ketamine 50 mg/mL Injection for healthcare professionals is available for reference in English at the following link:

<https://www.medicines.org.uk/emc/medicine/30569>

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 may differ from marketed ketamine injection (50 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 Ketamine 50 mg/mL Injection 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 Ketamine 50 mg/mL Injection, please contact Juno Pharmaceuticals Corp., 402-2233 Argentia Road, Mississauga, ON, L5N 2X7.

Appendices

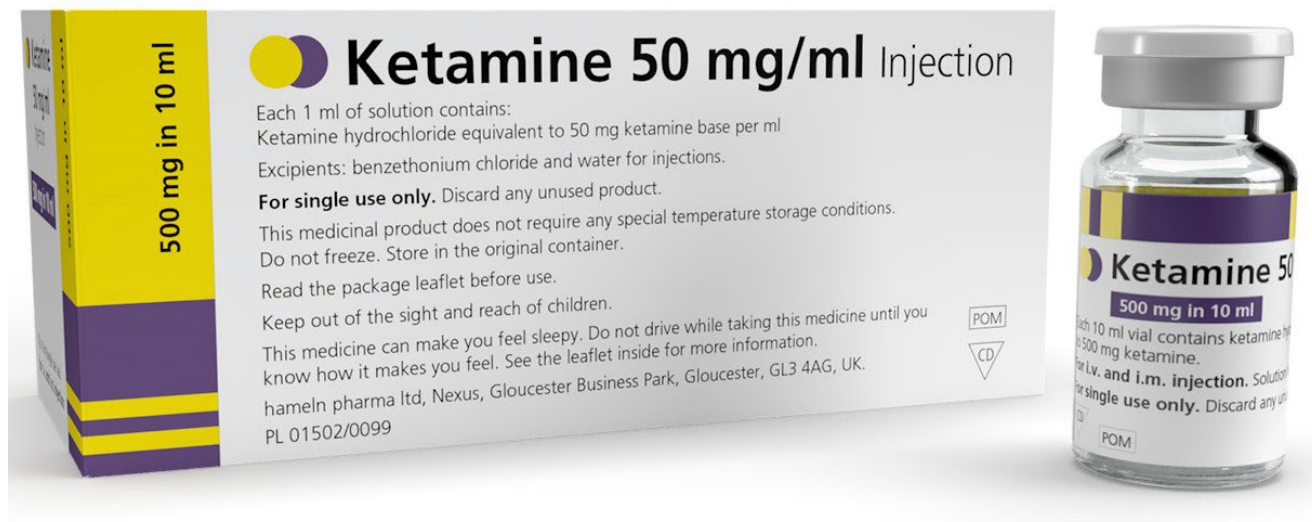
1. Images of UK-authorized Ketamine 50 mg/mL Injection

Sincerely,

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

Appendix 1 - Images of UK-Authorized Ketamine 50 mg/mL Injection

Product Photos





UK Vial Label

500 mg in 10 ml

Ketamine 50 mg/ml Injection

500 mg in 10 ml

Each 10 ml vial contains ketamine hydrochloride equivalent to 500 mg ketamine.

For i.v. and i.m. injection. Solution for injection or infusion

For single use only. Discard any unused product.

CD

POM

PL 01502/0099
hameln pharma ltd

Batch no.:
Expiry date:

47655/14/20

Plain text UK vial label

MAIN PANEL	
Ketamine 50 mg/ml Injection 500 mg in 10 ml Each 10 ml vial contains ketamine hydrochloride equivalent to 500 mg ketamine.	500 mg in 10 ml

For i.v. and i.m. injection. Solution for injection or infusion
 For single use only. Discard any unused product.
 (controlled drug symbol) (prescription only medicine symbol)
 PL 01502/0099
 hameln pharma ltd

SIDE PANEL

(2D barcode)

Batch no.:

Expiry date:

47655/14/20

UK Carton Label

Front and Top Panels



Ketamine 50 mg/ml Injection

500 mg in 10 ml

Solution for injection or infusion

Each 10 ml vial contains ketamine hydrochloride equivalent
 to 500 mg ketamine

10 x 10 ml single use vials **for i.v. and i.m. injection**



hameln

500 mg in 10 ml

Side Panels



**Ketamine
50 mg/ml
Injection**

500 mg in 10 ml

10 x 10 ml single use vials
for i.v. and i.m. injection

500 mg in 10 ml

Back panel

500 mg in 10 ml



Ketamine 50 mg/ml Injection

Each 1 ml of solution contains:

Ketamine hydrochloride equivalent to 50 mg ketamine base per ml

Excipients: benzethonium chloride and water for injections.

For single use only. Discard any unused product.

This medicinal product does not require any special temperature storage conditions.

Do not freeze. Store in the original container.

Read the package leaflet before use.

Keep out of the sight and reach of children.

This medicine can make you feel sleepy. Do not drive while taking this medicine until you know how it makes you feel. See the leaflet inside for more information.

hameln pharma ltd, Nexus, Gloucester Business Park, Gloucester, GL3 4AG, UK.

PL 01502/0099

POM

CD

Bottom Panel



Plain text UK carton label

FRONT and TOP PANEL	
Ketamine 50 mg/ml Injection	500 mg in 10 ml
500 mg in 10 ml	
Solution for injection or infusion	
Each 10 ml vial contains ketamine hydrochloride equivalent to 500 mg ketamine	
10 x 10 ml single use vials for i.v. and i.m. injection (logo) hameln	
SIDE PANELS	
Ketamine 50 mg/ml Injection	500 mg in 10 mL
500 mg in 10 ml	
10 x 10 ml single use vials for i.v. and i.m. injection	
BACK PANEL	
500 mg in 10 ml	
Ketamine 50 mg/ml Injection	
Each 1 ml of solution contains:	
Ketamine hydrochloride equivalent to 50 mg ketamine base per ml	
Excipients: benzethonium chloride	
and water for injections.	
For single use only. Discard any unused product.	
This medicinal product does not require any special temperature storage conditions.	
Do not freeze. Store in the original container.	
Read the package leaflet before use.	
Keep out of the sight and reach of children.	
This medicine can make you feel sleepy. Do not drive while taking this medicine until you know how it makes you feel. See the leaflet inside for more information.	
hameln pharma ltd, Nexus, Gloucester Business Park, Gloucester, GL3 4AG, UK. PL 01502/0099	
(prescription only medicine symbol) (controlled drug symbol)	

BOTTOM PANEL

