

Importation of UK-labelled Bupivacaine and Adrenaline (Epinephrine) Injection due to the current shortage of Canadian-authorized Sensorcaine with Epinephrine solution

SteriMax Inc.
2770 Portland Drive
Oakville, ON, Canada L6H 6R4

Date: May 30, 2024

Dear Healthcare professionals (physicians, anesthesiologists, nurses, hospital pharmacists), wholesalers, HealthPro and Medbuy GPO members.

There is a critical shortage of Sensorcaine with Epinephrine Solution in Canada. To help mitigate the shortage, Health Canada has permitted the exceptional, temporary importation and sale of Mercury Pharma's UK-labelled Bupivacaine and Adrenaline (Epinephrine) Injection with English only labels by SteriMax Inc., Oakville, ON.

Health Canada has accepted the addition of Mercury Pharma's Bupivacaine and Adrenaline (Epinephrine) Injection product to the [List of drugs for exceptional importation and sale](#).

In Canada, Sensorcaine with Epinephrine Solution is indicated for the production of local or regional anesthesia or analgesia with the following procedures:

- Local infiltration
- Peripheral minor or major nerve blocks
- Epidural block for surgery
- Epidural block by continuous infusion or intermittent bolus for postoperative or labour pain relief.

The UK-labelled product has the same active ingredients, strength (Bupivacaine hydrochloride 2.5mg and Adrenaline 5mcg per mL, Bupivacaine hydrochloride 5mg and Adrenaline 5mcg per mL), dosage form and route of administration.

The UK-labelled product has a different product composition (non-medicinal ingredients) than the Canadian marketed product. The UK-labelled product contains sodium acetate while the Canadian marketed product has sodium hydroxide and/ or hydrochloric acid in the formulation. Other non-medicinal ingredients remain same.

The UK-labelled product is available as 10 mL single use glass ampoule while the Canadian marketed product is available as 20 mL single use vials. Healthcare providers should exercise caution commensurate with the design of the ampoule when breaking the glass ampoule and aspirating the solution with a needle as per their established institutional standard of care.

Healthcare professionals are advised of the following:

- The UK-labelled products can be used in the same manner as the Canadian-authorized products.
- Healthcare professionals should refer to the Canadian Product Monograph for Sensorcaine with Epinephrine Injection available in English and French on the [Drug Product Database](#). The Canadian Product Monograph in the database contains information on the appropriate use of the product, including the:
 - indications
 - contraindications
 - warnings and precautions
 - adverse reactions
 - dosage and administration
 - handling instructions
- The UK-labelled products should be stored at below 25°C with storage of ampoules in a carton pack to protect from light. The solution should not be used if it is discolored in any way. The solution must not be stored in contact with metals e.g. needles or metal parts of syringes, as dissolved metal ions may cause swelling at the site of the injection.

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
Bupivacaine and Adrenaline (Epinephrine) Injection 0.25% w/v, 1 in 200,000	Solution (sterile), Bupivacaine hydrochloride 2.5mg/ mL, Adrenaline 5mcg/ mL Epidural administration	Sterile solution, preservative-free Each 10 mL single-dose clear glass ampoule contains 10 mL of solution. Available in cartons of 10 ampoules	United Kingdom PL 12762/0556	Mercury Pharmaceuticals Ltd. Dashwood House, 69 Old Broad Street London EC2M 1QS United Kingdom	SteriMax Inc., 2770 Portland Drive, Oakville, ON, L6H 6R4
Bupivacaine and Adrenaline (Epinephrine) Injection 0.5% w/v, 1 in 200,000	Solution (sterile), Bupivacaine hydrochloride 5mg/ mL, Adrenaline 5mcg/ mL Epidural administration	Sterile solution, preservative-free Each 10 mL single-dose clear glass ampoule contains 10 mL of solution. Available in cartons of 10 ampoules	United Kingdom PL 12762/0557		

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2770 Portland Drive, Oakville, Ontario, Canada L6H 6R4
Tel.: 905-890-0661, 1-800-881-3550 • Fax: 905-890-0508, 1-877-546-7667 • Web: www.sterimaxinc.com

Page 3 of 6

Information about UK-labelled Bupivacaine and Adrenaline (Epinephrine) Injection (Summary of Product Characteristics and Patient Information Leaflet) for health care professionals is available for reference in English at <https://www.medicines.org.uk/emc/product/6622/pil#about-medicine>.

Refer to Appendix – 01 for ampoule label and carton label of UK-labelled Bupivacaine and Adrenaline (Epinephrine) Injection, 0.25% w/v, 1 in 200,000.

Refer to Appendix – 02 for ampoule label and carton label of UK-labelled Bupivacaine and Adrenaline (Epinephrine) Injection, 0.5% w/v, 1 in 200,000.

Health care professionals are advised that aspects of the inner and outer labels and packaging of the UK-labelled products may differ from marketed Sensorcaine and Epinephrine injectable products in Canada. **Proper selection of the intended product must be verified to avoid confusion with other products and prevent medication errors.**

The UK-labelled products do 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-labelled Bupivacaine and Adrenaline (Epinephrine) Injection should be reported to SteriMax Inc. or to [Health Canada](http://www.healthcanada.gc.ca) or by calling toll-free at 1-866-234-2345. Refer to below for SteriMax contact information.

SteriMax Inc.,
2770, Portland Drive, Oakville, ON, L6H 6R4
Phone: +1-800-881-3550
Fax: +1-877-546-7667
E-mail: pv@sterimaxinc.com

You can report any suspected adverse reactions associated with the use of health products to Health Canada by:

- Calling toll-free at 1-866-234-2345; or
- Visiting MedEffect™ Canada's Web page on [Adverse Reaction Reporting](https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax.

Questions or concerns

For questions or concerns about UK-labelled Bupivacaine and Adrenaline (Epinephrine) Injection, please contact SteriMax Inc. at medinfo@sterimaxinc.com OR by phone at +1-800-881-3550 / +1-289-218-8682.

Appendices:

Appendix – 01: Ampoule label and carton label of UK-labelled Bupivacaine and Adrenaline (Epinephrine) Injection, 0.25% w/v, 1 in 200,000

Appendix – 02: Ampoule label and carton label of UK-labelled Bupivacaine and Adrenaline (Epinephrine) Injection, 0.5% w/v, 1 in 200,000

Appendix – 01: Ampoule label and carton label of UK-labelled Bupivacaine and Adrenaline (Epinephrine) Injection, 0.25% w/v, 1 in 200,000.

Lot:
 Exp:

10ml

**Bupivacaine and Adrenaline
 (Epinephrine) Injection**
 0.25% w/v, 1 in 200,000

Local infiltration, Peripheral nerve block, Sympathetic nerve block, Epidural block.

For single use only
 PL 12762/0556

**0.25%
 w/v
 Bupivacaine HCl
 1 in 200,000
 Adrenaline**

POM

MercuryPharma

777/13555620/xxxx
 LB-116450-01

Bupivacaine and Adrenaline (Epinephrine) Injection
 0.25% w/v, 1 in 200,000

10 Ampoules

**0.25%
 w/v
 Bupivacaine HCl
 1 in 200,000
 Adrenaline**

Each 10ml of sterile solution for injection contains 25mg anhydrous bupivacaine hydrochloride (2.5mg in 1ml) & 50 micrograms adrenaline (epinephrine) as the acid tartrate (1 in 200,000). Also contains sodium chloride, sodium metabisulphite (E223), and sodium acetate in water for injections.

See leaflet for further information.
 Use as directed by the doctor.
 Read the package leaflet before use.

Keep out of the sight and reach of children.

Do not store above 25°C.
 Keep the ampoules in the outer carton in order to protect from light.

The solution should not be used if it is discoloured in anyway.
 If only part used, discard the remaining solution.
 For single use only.

UK Only
 PL 12762/0556

POM

MercuryPharma

Mercury Pharmaceuticals Ltd, UK Holder
 Division: Pharmaceuticals
 100 Old Broad Street
 London, EC2M 1QS, United Kingdom

777/13555620/xxxx

090 0000888888 056

10ml

**Bupivacaine and
 Adrenaline (Epinephrine)
 Injection**
 0.25% w/v, 1 in 200,000

Local infiltration, Peripheral nerve block, Sympathetic nerve block, Epidural block.

**0.25%
 w/v
 Bupivacaine HCl
 1 in 200,000
 Adrenaline**

MercuryPharma

Appendix – 02: Ampoule label and carton label of UK-labelled Bupivacaine and Adrenaline (Epinephrine) Injection, 0.5% w/v, 1 in 200,000.

Lot:

Exp:

10ml

Bupivacaine and Adrenaline (Epinephrine) Injection
0.5% w/v, 1 in 200,000

Local infiltration, Peripheral nerve block, Sympathetic nerve block, Epidural block.

For single use only

PL 12762/0557

0.5% w/v Bupivacaine HCl
1 in 200,000 Adrenaline

POM

MercuryPharma

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LB-116447-01

Bupivacaine and Adrenaline (Epinephrine) Injection
0.5% w/v, 1 in 200,000

10 Ampoules

0.5% w/v Bupivacaine HCl
1 in 200,000 Adrenaline

Each 10ml of sterile solution for injection contains 50mg anhydrous bupivacaine hydrochloride (5mg in 1ml) & 50 micrograms adrenaline (epinephrine) as the acid tartrate (1 in 200,000). Also contains sodium chloride, sodium metabisulphite (E223), and sodium acetate in water for injections.

See leaflet for further information.
Use as directed by the doctor.
Read the package leaflet before use.

Keep out of the sight and reach of children.
Do not store above 25°C.
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If only part used, discard the remaining solution.
For single use only.

UK Only
PL 12762/0557

POM

MercuryPharma

Mercury Pharmaceuticals Ltd, MA Holder
Dashwood House, 60 Old Broad Street,
London, EC2M 1QS, United Kingdom

5 007620 001033

EXP: LOT: MFG DATE: 0000000000000000

10 Ampoules 0.5% w/v Bupivacaine HCl 1 in 200,000 Adrenaline

AMPHIPHILIC INK 4