Docusign Envelope ID: E21F6786-C205-8246-81B2-7033E3350082

Importation of Italian-Authorized BUPISEN iperbarica 7,5 mg/ml soluzione iniettabile (Bupivacaine Hydrochloride in Dextrose Injection) due to the Current Shortage of Canadian-Authorized Bupivacaine Hydrochloride in Dextrose Injection USP

2026/10/26

Audience
Healthcare professionals including hospital pharmacists, anaesthesiologists and those involved with administering spinal anaesthesia.

Key messages

- Due to a shortage of Bupivacaine Hydrochloride in Dextrose Injection USP in Canada, and given the medical necessity of this drug, Health Canada has permitted the exceptional, temporary importation and sale of Italian-authorized BUPISEN iperbarica 7,5 mg/ml soluzione iniettabile (Bupivacaine Hydrochloride in Dextrose Injection), with Italian-only labels.

- The Italian-authorized product has the same active ingredient (bupivacaine hydrochloride), strength (7.5 mg/mL), dosage form and container closure (sterile solution in single-dose glass ampoule), and route of administration (intrathecal) as the Canadian-authorized product by Formative Pharma Inc. However, there are important differences between these products, including the volume per ampoule (3 mL for Italian-authorized product versus 2 mL for Canadian-authorized product) and special handling instructions.

- Healthcare professionals are advised to:
    - Be aware of important differences between the Italian-authorized and the Canadian-authorized Bupivacaine Hydrochloride in Dextrose Injection products (see the Information for healthcare professionals section and Table 1).

    - Refer to the Canadian Product Monograph for Bupivacaine Hydrochloride in Dextrose Injection USP, 7.5 mg/mL by Formative Pharma Inc. (DIN 02536714), available in English and French on Health Canada's Drug Product Database, for information on authorized indications, contraindications, dosage, storage, other safety information, and special handling instructions.

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- Be aware that the autoclaving instructions in the Canadian Product Monograph do not apply to the Italian-authorized product, as it must not be re-sterilized.

What is the issue?

There is a shortage of Bupivacaine Hydrochloride in Dextrose Injection USP in Canada. Given the medical necessity of Bupivacaine Hydrochloride in Dextrose Injection USP and the need to maintain continuity of supply in Canada, Health Canada has permitted the exceptional, temporary importation and sale of Italian-authorized BUPISEN iperbarica 7,5 mg/ml soluzione iniettabile (Bupivacaine Hydrochloride in Dextrose Injection) with Italian-only labels.

Healthcare professionals should be aware of important differences between the Italian-authorized and Canadian-authorized products (see Information for healthcare professionals section).

Products affected

Brand name	**Dosage form and route of administration**	**Country of authorization and identifying code**	**Manufactured By**	**Importer in Canada**
BUPISEN iperbarica 7,5 mg/ml soluzione iniettabile	Solution, Intrathecal (Spinal)	Italy MA No.034171215	Industria Farmaceutica Galenica Senese S.r.l.	Formative Pharma Inc.

Background information

In Canada, Bupivacaine Hydrochloride in Dextrose Injection USP, 7.5 mg/mL is indicated for the production of local or regional anaesthesia and analgesia with the following procedure:

- Subarachnoid (spinal) blocks

Standard procedures for subarachnoid (spinal) blocks should be followed.

Information for healthcare professionals

This product should be administered by appropriately trained healthcare professionals familiar with its actions, characteristics, and hazards.

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The Italian-authorized BUPISEN iperbarica 7,5 mg/ml soluzione iniettabile (Bupivacaine Hydrochloride in Dextrose Injection) product has the same active ingredient (bupivacaine hydrochloride), strength (7.5 mg/mL), dosage form and container closure (sterile solution in single-dose glass ampoule), and route of administration (intrathecal) as the Canadian-authorized product by Formative Pharma Inc. The Italian-authorized product, like the Canadian-authorized product, contains no antimicrobial preservative. However, the Italian-authorized product has some important differences from the Canadian-authorized product that should be considered prior to use (Table 1).

Table 1: Key differences between Italian-authorized BUPISEN iperbarica 7,5 mg/ml soluzione iniettabile (Bupivacaine Hydrochloride in Dextrose Injection) and Canadian-authorized Bupivacaine Hydrochloride in Dextrose Injection USP

	Italian-authorized drug product for importation by Industria Farmaceutica Galenica Senese S.r.l.	**Canadian-authorized drug product by Formative Pharma Inc.**
Product Brand Name	BUPISEN iperbarica 7,5 mg/ml soluzione iniettabile	Bupivacaine Hydrochloride in Dextrose Injection USP
Expression of Strength	7,5 mg/mL	15 mg/2 mL (7.5 mg/mL) 0.75%
Identifying Code	MA No.034171215	DIN 02536714
Volume per ampoule	**3 mL**	2 mL
Packaging	1 x 3 mL ampoule	10 x 2 mL ampoules
Special Handling Instructions	**Must not be re-sterilized via autoclave.**	May be autoclaved. Autoclave at 15-pound pressure, 121°C (250°F) for 15 minutes.
Storage and Stability	This medicinal product does not require any special storage conditions.	Store at 15-30°C.
Labelling Language	Italian	English/French

Images of the Italian-authorized product can be found in **Appendix 1.**

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Healthcare professionals are advised of the following:

- The Italian-authorized product has a different brand name, carton and ampoule label, and pack size (1 x 3 mL ampoule instead of 10 x 2 mL ampoules) than the Canadian-authorized product by Formative Pharma Inc. (see Appendix 1). Proper selection of the intended product must be verified to avoid confusion with other products and to prevent medication errors.
- Although both products have the same strength (7.5 mg/mL), the expression of strength displayed on the Italian-authorized carton and ampoule appears as 7,5 mg/mL and is missing the total amount of bupivacaine hydrochloride per total volume (22.5 mg/3 mL). The Canadian-authorized product displays the strength as 0.75%, 7.5 mg/mL and 15 mg/2 mL on both the carton and ampoule.
- The Italian-authorized product labels do not indicate that the product is for **single-dose** use. Additionally, sterility is not explicitly stated on the ampoule label; however, the product is **sterile**.
- Unlike the Canadian-authorized product, the Italian-authorized product labelling does not identify the product as being for **Spinal Use Only**.
- The Canadian-authorized product may be autoclaved; however, the Italian-authorized product **must NOT be re-sterilized**. The Italian-authorized product is supplied in an individually wrapped sterile pouch which may be wiped before use.
- The precautionary statement, "Do not use if solution is discoloured or contains a precipitate", which appears on the label of the Canadian-authorized product, is not found on the label of the Italian-authorized product.
- The Canadian Product Monograph specifies that use in patients younger than 18 years of age is NOT recommended. Although this statement is not included in the Italian-authorized product information, the same recommendation applies.
- Refer to the Canadian Product Monograph for Bupivacaine Hydrochloride in Dextrose Injection USP, 7.5 mg/mL by Formative Pharma Inc. (DIN 02536714), available in English and French on Health Canada's Drug Product Database, for information on authorized indications, contraindications, dosage, storage, other safety information, and special handling instructions.
- The Italian-authorized product carton includes an Italian leaflet that contains information for multiple bupivacaine hydrochloride products and strengths not available in Canada, including indications and doses that differ from the Canadian Product Monograph. Refer to the English and French translations of the BUPISEN iperbarica 7.5 mg/ml soluzione iniettabile leaflet for additional product-specific information.
- The Italian-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.
- Consult the English and French translation of the Summary of Product

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Characteristics (SmPC) for Italian-authorized BUPISEN iperbarica 7,5 mg/ml soluzione iniettabile for additional product-specific information.

Action taken by Health Canada

To help mitigate the shortage of Bupivacaine Hydrochloride in Dextrose Injection USP in Canada, Health Canada has permitted the exceptional, temporary importation and sale of Italian-authorized BUPISEN iperbarica 7,5 mg/ml soluzione iniettabile (Bupivacaine Hydrochloride in Dextrose Injection) and has added this product to the List of Drugs for Exceptional Importation and Sale.

Health Canada has worked with Formative Pharma Inc. to prepare this alert for Italian-authorized BUPISEN iperbarica 7,5 mg/ml soluzione iniettabile. Health Canada is communicating this important safety information to healthcare professionals and Canadians via the Recalls and Safety Alerts Database on the Healthy Canadians Web Site. This communication will be further distributed through the MedEffect™ e-Notice email notification system.

Report health or safety concerns

Managing marketed health product-related side effects depends on healthcare professionals and consumers reporting them. Any case of serious or unexpected side effects in patients receiving Italian-authorized BUPISEN iperbarica 7,5 mg/ml soluzione iniettabile should be reported to Formative Pharma Inc. or Health Canada.

Formative Pharma Inc.
4145 North Service Road, Suite 200
Burlington, ON
L7L 6A3

Telephone: 1-855-808-9528

To correct your mailing address or fax number, contact Formative Pharma Inc.

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 (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) for information on how to report online, by mail or by fax.

For other health product inquiries related to this communication, contact Health Canada at:

Regulatory Operations and Enforcement Branch
E-mail: hpce-cpsal@hc-sc.gc.ca
Telephone: 1-800-267-9675

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Original signed by
Lee Mangubat
President and CEO

DocuSigned by:
Lee Mangubat
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Appendix 1

Image of Italian-authorized BUPISEN iperbarica 7,5 mg/ml soluzione iniettabile, **Ampoule and Carton**:



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Image of Italian-authorized BUPISEN iperbarica 7,5 mg/ml soluzione iniettabile, **Ampoule Label**:



English Translation:

Bupisen 7.5 mg/ml hyperbaric solution for injection
Bupivacaine hydrochloride
3 ml

Lot no.:
Expiry:

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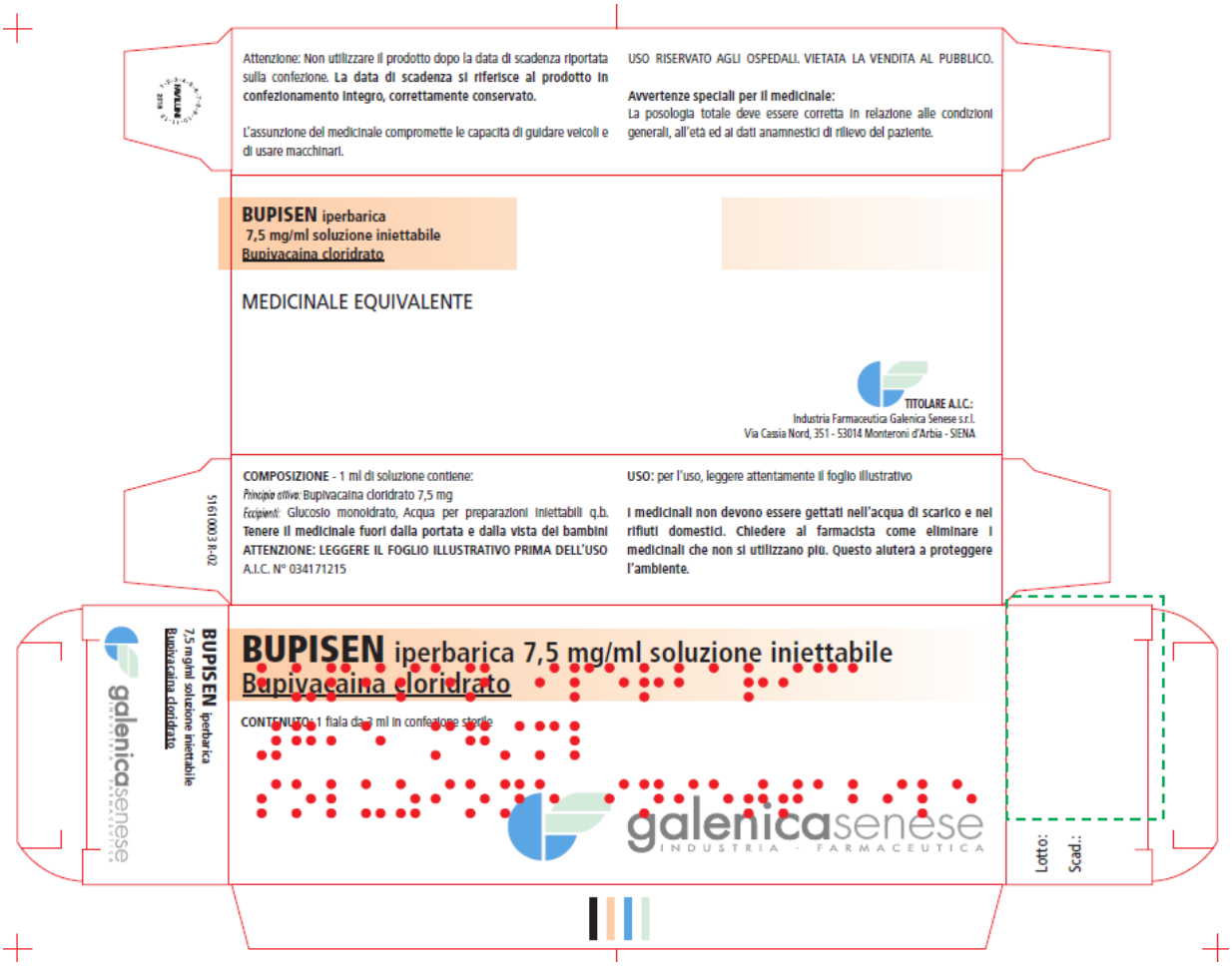
Image of Italian-authorized BUPISEN iperbarica 7,5 mg/ml soluzione iniettabile,
Outer Carton:



English translation of outer carton label:

Main Panel

BUPISEN 7.5 mg/ml hyperbaric solution for injection
Bupivacaine hydrochloride
CONTENTS: 1 vial of 3 ml in sterile pack

The Braille text reads: Bupisen 7.5 mg/ml hyperbaric solution for injection

Back Panel

BUPISEN 7.5 mg/ml hyperbaric solution for injection
Bupivacaine hydrochloride
GENERIC MEDICINE
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Side Panel 1

Warning: Do not use this medicine after the expiry date printed on the pack. **The expiry date applies to the product in unopened and properly stored pack.**

Taking this medicine impairs the ability to drive vehicles and operate machinery.

FOR HOSPITAL USE ONLY. NOT FOR SALE TO THE PUBLIC.

Special warnings for this medicine:
The total dosage must be adjusted according to the patient's general condition, age and relevant medical history.

Side Panel 2

COMPOSITION - 1 ml of solution contains:
Active substance: Bupivacaine hydrochloride 7.5 mg
Excipients: Glucose monohydrate, Water for injection as needed
Keep this medicine out of sight and reach of children
WARNING: READ THIS INSTRUCTIONS FOR USE LEAFLET BEFORE USE

USE: read this Instructions for Use Leaflet carefully before use

Medicines must not be disposed of in the drain or with household waste. Ask your pharmacist how to dispose of medicines you no longer use. This will help protect the environment.

Side Panel 3

BUPISEN 7.5 mg/ml hyperbaric solution for injection
Bupivacaine hydrochloride

Side Panel 4

Lot no.:
Expiry: