Temporary importation of US-labelled Nesacaine-MPF (Chloroprocaine HCl, USP) 2% to address a medical need in Canada

2021/02/05

Audience
Healthcare professionals including intensivists, anesthesiologists, anesthesiology nurses, pharmacists, dental surgeons, gastroenterologists, chiefs of medicine in hospitals, Intensive Care Unit (ICU) and Emergency Room (ER) medical staff.

Key messages

In order to address a medical need for an anaesthetic agent intended for short-duration surgical procedures and ambulatory procedures, Health Canada has not objected to the temporary importation and distribution of US-labelled Nesacaine-MPF (chloroprocaine hydrochloride, USP) 2% in Canada as these products are no longer marketed in Canada.

- **Nesacaine-MPF (chloroprocaine hydrochloride, USP) 2% ("MPF" for "methylparaben free") is a short-acting local anaesthetic agent.**
- **Nesacaine-MPF (chloroprocaine hydrochloride, USP) 2%, in single dose vials without preservative and without EDTA, is indicated in adults for the production of local anaesthesia by infiltration, peripheral and central nerve block, including lumbar and caudal epidural blocks.**
- **Nesacaine-MPF (chloroprocaine hydrochloride, USP) 2% should NOT be used for spinal anaesthesia (subarachnoid administration).**
- **Healthcare professionals are advised that:**
    - **For proper use of the product, healthcare professionals should refer to the US product package insert for the full prescribing information, with particular attention to the Indications and Usage, Warnings and Dosage and Administration sections.**
    - **Multiple foreign-labelled chloroprocaine products with differing indications, uses and strengths may be imported simultaneously for use in Canada. The product label should be verified at the point of use in order to confirm appropriate product selection according to the desired route of administration. This product may differ from other chloroprocaine products - review the package insert for this product prior to use.**

- **The product is preservative free, therefore with a very limited shelf-life. Unused product remaining in the vial after a procedure should be discarded.**

What is the issue?
In order to address a medical need for an anaesthetic agent intended for short-duration surgical procedures and ambulatory procedures, Health Canada has not objected to the temporary importation and distribution of US-labelled Nesacaine-MPF (chloroprocaine hydrochloride, USP) 2% in Canada as these products are no longer marketed in Canada.

Products affected
Nesacaine-MPF (chloroprocaine hydrochloride, USP) 2% in 20 mL vials manufactured by Fresenius Kabi USA, LLC.

Background information

The temporary importation of Nesacaine-MPF (chloroprocaine hydrochloride, USP) 2% will provide access to Nesacaine injection in Canada to address a medical need.

Information for healthcare professionals

Healthcare professionals are advised that:

- The key formulation and labelling characteristics of Nesacaine-MPF (chloroprocaine hydrochloride, USP) 2%, are indicated in the table below.

Product Name	Nesacaine-MPF (chloroprocaine hydrochloride, USP) 2% injection
Active Substance	Chloroprocaine hydrochloride
Concentration	2% (20 mg per mL)
Fill Volume	20 mL
Format	Single Dose Vial
Other	Methylparaben free, EDTA free
Manufacturer	Fresenius Kabi USA, LLC

- **For proper use of the product, healthcare professionals should refer to the US product package insert for the full prescribing information, with particular attention to the Indications and Usage, Warnings and Dosage and Administration sections.**

- Healthcare professionals should **not** refer to Canadian product monographs of chloroprocaine products that have been discontinued.

Important information highlighted from the US-labelled Nesacaine-MPF (chloroprocaine hydrochloride, USP) 2% injection package insert:

- Nesacaine-MPF (chloroprocaine hydrochloride, USP) 2% is contraindicated in patients hypersensitive (allergic) to drugs of the para-aminobenzoic acid (PABA) ester group.

- Lumbar and caudal epidural anaesthesia should be used with extreme caution in persons with the following conditions: existing neurological disease, spinal deformities, septicemia, and severe hypertension.

- Local anaesthetics should only be employed by clinicians who are well versed in diagnosis and management of dose related toxicity and other acute emergencies which might arise.

- Nesacaine-MPF (chloroprocaine hydrochloride, USP) 2% contains no preservative; discard unused product remaining in vial after initial use.

- The safety and effective use of chloroprocaine depend on proper dosage, correct technique, adequate precautions and readiness for emergencies. Resuscitative equipment, oxygen and other resuscitative drugs should be available for immediate use.

- Careful and constant monitoring of cardiovascular and respiratory (adequacy of ventilation) vital signs and the patient's state of consciousness should be accomplished after each local anaesthetic injection. It should be kept in mind at such times that restlessness, anxiety, tinnitus, dizziness, blurred vision, tremors, depression or drowsiness may be early warning signs of central nervous system toxicity.

- Since ester-type local anaesthetics are hydrolyzed by plasma cholinesterase produced by the liver, chloroprocaine should be used cautiously in patients with hepatic disease.

- Local anaesthetics should also be used with caution in patients with impaired cardiovascular function.

The US product package insert can be found on the Fresenius Kabi Canada Ltd. website at the following links:

English version
https://www.fresenius-kabi.com/en-ca/documents/Package-Insert-Nesacaine-MPF-En.pdf

French version
https://www.fresenius-kabi.com/fr-ca/documents/Package-Insert-Nesacaine-MPF-Fr.pdf

Healthcare professionals should be aware that the US-labelled product does not have a DIN or barcode that will scan in Canadian medication use systems. A facility-generated sticker or overlabel may be required to enable barcode scanning and allow proper identification of the product being dispensed. Proper selection of the intended product must be confirmed to avoid confusion with other products.

Report health or safety concerns

Any adverse reaction in patients receiving Nesacaine-MPF (chloroprocaine hydrochloride, USP) 2% should be reported to Fresenius Kabi Canada Ltd. or Health Canada.

Fresenius Kabi Canada Ltd.
E-mail: Canada_Vigilance@fresenius-kabi.com
Telephone: 1-877-779-7760

To correct your mailing address or fax number, contact Fresenius Kabi Canada Ltd.

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) for information on how to report online, by mail or by fax.

Original signed by

Darinca Man
Manager, Vigilance/National Safety Officer
Fresenius Kabi Canada Ltd.

Images of the US-labelled Nesacaine-MPF (chloroprocaine hydrochloride, USP) 2% injection

Vial

Vial Label

French Translation of Vial Label Text

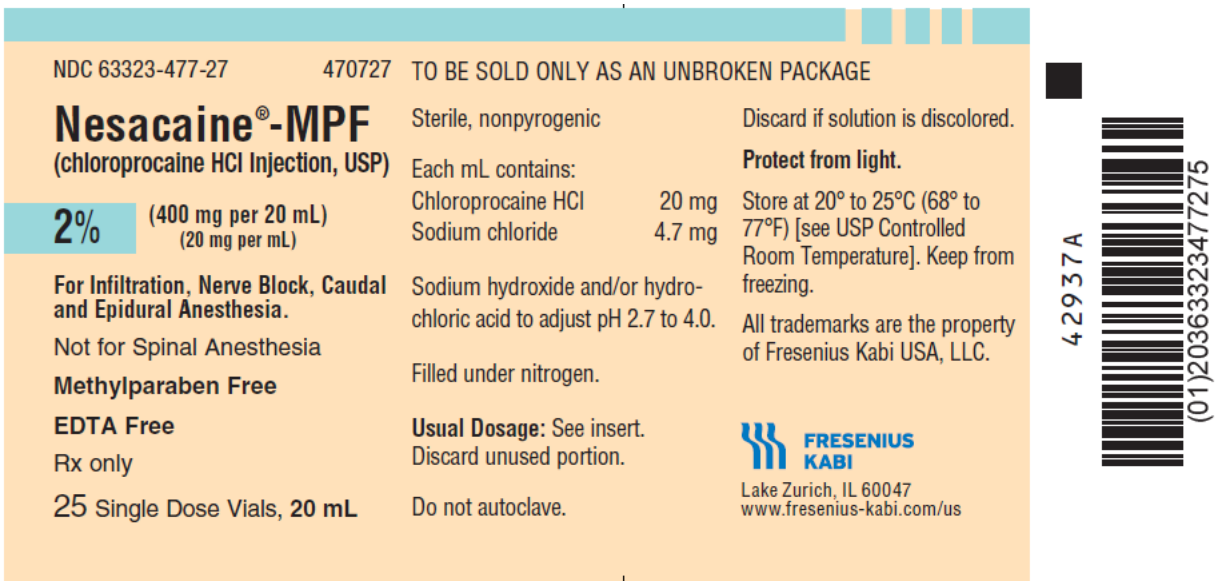
NDC 63323-477-01 470727

Nesacaine[MD]–MPF 2 %
(chlorhydrate de chloroprocaïne injectable, USP)
(400 mg par 20 mL)
(20 mg par mL)

Pour infiltration, bloc nerveux et anesthésie caudale et péridurale.
Pas pour l'anesthésie rachidienne
Sans méthylparabène Sans EDTA
Fiole à dose unique de 20 mL

Stérile, apyrogène
Ne pas passer à l'autoclave.
Jeter si la solution a changé de couleur.
Protéger de la lumière.
Conserver entre 20° et 25 °C (68° et 77 °F) [voir les directives USP de conservation à la température ambiante contrôlée].
Garder à l'abri du gel.
Rx seulement

Outer Tray Label



French Translation of Outer Tray Label Text

NDC 63323-477-27 470727

Nesacaine[MD]–MPF 2 %
(chlorhydrate de chloroprocaïne injectable, USP)
(400 mg par 20 mL)
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Pour infiltration, bloc nerveux et anesthésie caudale et péridurale.
Pas pour l'anesthésie rachidienne
Sans méthylparabène
Sans EDTA
25 fioles à dose unique de 20 mL
Stérile, apyrogène
Chaque mL contient :
Chlorhydrate de chloroprocaïne 20 mg
Chlorure de sodium 4,7 mg
Hydroxyde de sodium et/ou acide chlorhydrique pour ajuster le pH entre 2,7 et 4,0.
Remplissage sous azote.
Posologie habituelle : Voir le feuillet d'emballage.
Jeter toute portion inutilisée.
Ne pas passer à l'autoclave.
Jeter si la solution a changé de couleur.
Protéger de la lumière.
Conserver entre 20° et 25 °C (68° et 77 °F) [voir les directives USP de conservation à la température ambiante contrôlée]. Garder à l'abri du gel.
Toutes les marques de commerce sont la propriété de Fresenius Kabi USA, LLC.
À VENDRE UNIQUEMENT SOUS LA FORME D'UN EMBALLAGE INTACT
Rx seulement