

*B. Braun of Canada Ltd.
2000 Ellesmere Road, 16
Scarborough, Ontario
Canada, M1H 2W4*

Information on the importation of US-labelled Clorotekal® (chloroprocaine hydrochloride 10 mg/mL) in Canada

To: Healthcare professionals including hospital pharmacists and anesthesiologists

IMPORTANT

- 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 Clorotekal® (chloroprocaine hydrochloride 10 mg/mL) in Canada as these products are no longer marketed in Canada.
- Chloroprocaine hydrochloride solution for injection is a short-acting local anaesthetic agent. The US-labelled Clorotekal® (chloroprocaine hydrochloride **10 mg/mL**) product is intended **for intrathecal use only**. This product is indicated for intrathecal injection for the production of subarachnoid block (spinal anaesthesia) in adults undergoing surgical procedures. Indicated procedures include those suitable for Clorotekal®'s short duration of action.
- The US-labelled Clorotekal® (chloroprocaine hydrochloride 10 mg/mL) product is **not** approved for use in pediatric or adolescent patients.
- The US-labelled Clorotekal® (chloroprocaine hydrochloride 10 mg/mL) does **not** contain methylparaben (preservative). This product is intended for single-use only.
- There are differences in the strength, route of administration and indications between the US-labelled Clorotekal® (chloroprocaine hydrochloride 10 mg/mL) product and chloroprocaine products previously marketed in Canada.
- **Multiple foreign-labelled chloroprocaine products with differing indications, routes of administration 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 US-labelled Clorotekal® is labelled in English only, including the package insert. French translations of the inner and outer labels and a link to the French-translated package insert have been provided below.
- For proper use of the product, healthcare professionals should refer to the US-authorized product information for Clorotekal® (chloroprocaine hydrochloride 10 mg/mL) and should **not** refer to Canadian product monographs of chloroprocaine products that have been discontinued.
- Full digital copies (English and French-translation) of the US-labelled Clorotekal® (chloroprocaine hydrochloride 10 mg/mL) solution for injection package insert can be found in the links below:

Clorotekal® (EN):

<https://www.bbraun.ca/en/products-and-therapies/regional-anesthesia-and-pain-management/clorotekal-additional-information.html#>

Clorotekal® (FR):

<https://www.bbraun.ca/en/products-and-therapies/regional-anesthesia-and-pain-management/clorotekal-additional-information.html#>

- US-labelled Clorotekal® (chloroprocaine hydrochloride 10 mg/mL) solution for injection key highlights:

Presentation	Single-dose sterile, clear, colourless solution in a Type I (USP) glass ampoule
Strength	50 mg of chloroprocaine hydrochloride in 5 mL aqueous solution (concentration: 10 mg/mL) equivalent to 44.05 mg/5 mL (8.81 mg/mL) chloroprocaine.
Storage Conditions	Stored at 20°C to 25°C; Do not refrigerate or freeze.
Inactive ingredients	Hydrochloric acid 1N (for pH adjustment), sodium chloride, water for injection.

- The US-labelled Clorotekal® (chloroprocaine hydrochloride 10 mg/mL) product does not have a DIN and the barcode may not scan in Canadian medication use software. A facility-generated sticker may be required to enable barcode scanning and allow proper identification of the product being dispensed and administered. Proper selection of the intended product must be confirmed to avoid confusion with other injectable products.

Adverse drug reactions associated with the use of Clorotekal® (chloroprocaine hydrochloride 10mg/mL) should be reported to B. Braun of Canada Ltd. at 1-800-227-2862 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.

Images of the US-labelled Clorotekal® (chloroprocaine hydrochloride 10 mg/mL) solution for injection (English):

Inner Label

NDC 0264-7055-05
REF D7055

Clorotekal®
(Chloroprocaine HCl Injection, USP)
50 mg/5 mL
(10 mg/mL)

Rx Only Injection For Intrathecal Use Only
1 mL contains 10 mg Chloroprocaine HCl, equal to 8.81 mg Chloroprocaine base, Sodium Chloride, Hydrochloric Acid 1N, Water for Injection, 5 mL Single Dose Ampule. Discard Unused Portion. See package insert for dosage information

1%

68699 01

LOT

EXP

LD-579-1

B | BRAUN

(01) 10302647055052

Outer Label

68699 03
LD-579-1

B | BRAUN

(01) 10302647055101

Injection For Intrathecal Use Only

Clorotekal®
(Chloroprocaine HCl Injection, USP)
50 mg/5 mL
(10 mg/mL)

1%

Rx Only
10 Single Dose Ampules x 5 mL
Discard Unused Portion

B | BRAUN

NDC 0264-7055-10
REF D7055

Injection For Intrathecal Use Only

Usual Dose:
See Package Insert for Dosage Information

Each mL contains:
10 mg Chloroprocaine HCl, equivalent to 8.81 mg Chloroprocaine base, Sodium Chloride, Hydrochloric Acid 1N, Water for Injection.

GTIN (01)
LOT (10)
EXPIRY
SERIAL (21)

60302647055101
LLLLL
MM/YYYY
0000000000000000

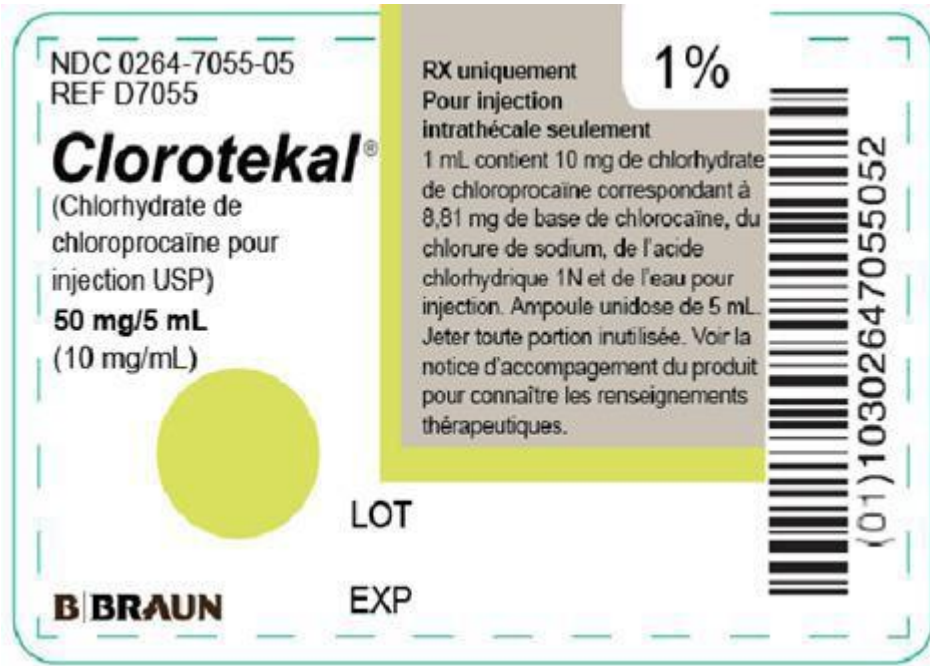
Do not refrigerate or freeze. Store at 20°C to 25°C (68°F to 77°F)
[See USP Controlled Room Temperature], Retain in carton until time of use. Protect from light.
Read the package Insert Labeling before use. Keep out of the reach and sight of children.
Use immediately after first opening, for single use only. Any unused solution should be discarded.

Manufactured for:
B. Braun Medical Inc.
Bethlehem, PA 18018-3524 USA
1-800-227-2862
Made in Switzerland.

Manufactured by:
Sintetica S.A, Switzerland
Clorotekal is a registered trademark of Sintetica S.A.

French-translations of US-labelled Clorotekal® (chloroprocaine hydrochloride 10 mg/mL) solution for injection:

Inner Label



Outer Label



Thank you,



B. Braun of Canada Ltd.
6711 Mississauga Rd, Unit 504
Mississauga, ON, Canada L5N 2W3