

October 19, 2023

Ropivacaine Hydrochloride Injection, USP Product Label Changes

Dear Valued Customer,

Fresenius Kabi Canada would like to advise that changes have been made to three (3) formats of our **Ropivacaine Hydrochloride Injection, USP** product label:

- **Labelling:** The blister labels for the below mentioned formats are now printed with black & white ink and the linear barcode has been replaced with a 2D barcode containing GTIN, lot number, and expiry information. The ampoule labels remain unchanged.

A more detailed look at the current versus new labelling can be found on the next page.

DIN	Fresenius Kabi Product Code	MDP Product Code	McKesson Product Code	Product Description	Availability Date
02439387	ABA1823	974900	124858	Ropivacaine Hydrochloride Injection, USP 5 mg/mL Ampoule 10 mL	October 19, 2023
02439409	ABA1846	974894	124903	Ropivacaine Hydrochloride Injection, USP 10 mg/mL Ampoule 10 mL	October 19, 2023
02439409	ABA1847	974882	124915	Ropivacaine Hydrochloride Injection, USP 10 mg/mL Ampoule 20 mL	October 25, 2023

Please note, during this transition period the current labeled product may still be in distribution until inventory is depleted.

Labelling Changes:

	Current Blister Label	*NEW* Blister Label
Ropivacaine Hydrochloride Injection, USP 5 mg/mL Ampoule 10 mL	<p>10 mL ABA 1823 DIN 02439387 Local Anesthetic. Single use. Discard unused portion. Preservative free. Dosage and administration: See package insert. Store at 15 °C to 30 °C. Do not freeze. Do not autoclave. Product Monograph available on request. The ampoule is not made with natural rubber latex.</p> <p>0.5 mg / mL 0.5 % w / v</p> <p>50 mg / 10 mL (5 mg / mL)</p> <p>1% w / v Sterile Solution Stérile For Infiltration, Nerve Block and Epidural Administration Only</p> <p>Concerns / Questions / Problèmes? Fresenius Kabi Canada Ltd. M9W 0C8, 1-877-821-7724</p> <p>LOT 99XXXX99 EXP MM-YYYY</p> <p>629336003044</p>	<p>10 mL ABA 1823 DIN 02439387 Local Anesthetic. Single use. Discard unused portion. Preservative free. Dosage and administration: See package insert. Store at 15 °C to 30 °C. Do not freeze. Do not autoclave. Product Monograph available on request. The ampoule is not made with natural rubber latex.</p> <p>0.5 mg / mL (5 mg / mL)</p> <p>0.5 % w / v</p> <p>50 mg / 10 mL (5 mg / mL)</p> <p>1% w / v Sterile Solution Stérile For Infiltration, Nerve Block and Epidural Administration Only</p> <p>Concerns / Questions / Problèmes? Fresenius Kabi Canada Ltd. M9W 0C8, 1-877-821-7724</p> <p>LOT 99XXXX99 EXP MM-YYYY</p> <p>GTIN: 00629336003044</p>
Ropivacaine Hydrochloride Injection, USP 10 mg/mL Ampoule 10 mL	<p>10 mL ABA 1846 DIN 02439409 Local Anesthetic. Single use. Discard unused portion. Preservative free. Dosage and administration: See package insert. Store at 15 °C to 30 °C. Do not freeze. Do not autoclave. Product Monograph available on request. The ampoule is not made with natural rubber latex.</p> <p>100 mg / 10 mL (10 mg / mL)</p> <p>1% w / v Sterile Solution Stérile For Epidural Administration Only</p> <p>Concerns / Questions / Problèmes? Fresenius Kabi Canada Ltd. M9W 0C8, 1-877-821-7724</p> <p>LOT 99XXXX99 EXP MM-YYYY</p> <p>629336003068</p>	<p>10 mL ABA 1846 DIN 02439409 Local Anesthetic. Single use. Discard unused portion. Preservative free. Dosage and administration: See package insert. Store at 15 °C to 30 °C. Do not freeze. Do not autoclave. Product Monograph available on request. The ampoule is not made with natural rubber latex.</p> <p>100 mg / 10 mL (10 mg / mL)</p> <p>1% w / v</p> <p>Sterile Solution Stérile For Epidural Administration Only</p> <p>Concerns / Questions / Problèmes? Fresenius Kabi Canada Ltd. M9W 0C8, 1-877-821-7724</p> <p>LOT 99XXXX99 EXP MM-YYYY</p> <p>GTIN: 00629336003068</p>
Ropivacaine Hydrochloride Injection, USP 10 mg/mL Ampoule 20 mL	<p>20 mL ABA 1847 DIN 02439409 Local Anesthetic. Single use. Discard unused portion. Preservative free. Dosage and administration: See package insert. Store at 15 °C to 30 °C. Do not freeze. Do not autoclave. Product Monograph available on request. The ampoule is not made with natural rubber latex.</p> <p>200 mg / 20 mL (10 mg / mL)</p> <p>1% w / v Sterile Solution Stérile For Epidural Administration Only</p> <p>Concerns / Questions / Problèmes? Fresenius Kabi Canada Ltd. M9W 0C8, 1-877-821-7724</p> <p>LOT 99XXXX99 EXP MM-YYYY</p> <p>629336003082</p>	<p>20 mL ABA 1847 DIN 02439409 Local Anesthetic. Single use. Discard unused portion. Preservative free. Dosage and administration: See package insert. Store at 15 °C to 30 °C. Do not freeze. Do not autoclave. Product Monograph available on request. The ampoule is not made with natural rubber latex.</p> <p>200 mg / 20 mL (10 mg / mL)</p> <p>1% w / v</p> <p>Sterile Solution Stérile For Epidural Administration Only</p> <p>Concerns / Questions / Problèmes? Fresenius Kabi Canada Ltd. M9W 0C8, 1-877-821-7724</p> <p>LOT 99XXXX99 EXP MM-YYYY</p> <p>GTIN: 00629336003082</p>

If you would like to obtain more information on this product, please contact your hospital representative or our Customer Service Department at (877) 821-7724.

Sincerely,



Joseph Le
Senior Manager, Commercial Operations & Analytics
joseph.le@fresenius-kabi.com