

22nd December 2023

Dear Healthcare Professional,

Availability of XYLOCAINE-MPF 2 per cent with epinephrine 1:200,000 (400mg lidocaine hydrochloride and 0.1mg epinephrine in 20mL) injection, USP single dose vial (USA) - under alternative supply arrangement of Section 19A of the Therapeutic Goods Act.

Due to the shortage of the Australian registered **XYLOCAINE 2% with Epinephrine 1:200,000 20ml ampoule**, Reach Pharmaceuticals has arranged the supply of an alternative product called **XYLOCAINE 2% with Epinephrine 1:200,000 20ml ampoule (USA)** registered and marketed in the USA.

XYLOCAINE-MPF 2 per cent with epinephrine 1:200,000 (400mg lidocaine hydrochloride and 0.1mg epinephrine in 20mL) injection, USP single dose vial (USA) is not registered in Australia and supply is authorised under an exemption granted by the Therapeutic Goods Administration (TGA) under Section 19A of the *Therapeutic Goods Act, 1989* until 30th April 2024 for the following indication(s):

For the production of local or regional anaesthesia by the following techniques: – infiltration, – intravenous regional anaesthesia – excluding solutions with adrenaline (epinephrine) acid tartrate, – peripheral nerve block such as intercostal block, – major plexus block such as brachial plexus block, – epidural block, – subarachnoid block.

Please refer to the Australian Product Information for recommended dosing for the above indications.

Please note: CONTAINS SULFITES

XYLOCAINE-MPF 2 per cent with epinephrine 1:200,000 (400mg lidocaine hydrochloride and 0.1mg epinephrine in 20mL) injection, USP single dose vial (USA) contains sodium metabisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. Use **XYLOCAINE-MPF 2 per cent with epinephrine 1:200,000 (400mg lidocaine hydrochloride and 0.1mg epinephrine in 20mL) injection, USP single dose vial (USA)** is contraindicated in patients with hypersensitivity to sulfite-containing medications.

Please find a summary of differences between the ARTG-registered product and section 19A approved product.

	ARTG Registered Product	Section 19A Approved Product
	XYLOCAINE 2% WITH ADRENALINE 1:200,000 20mL injection vial	XYLOCAINE-MPF 2 per cent with epinephrine 1:200,000 (400mg lidocaine hydrochloride and 0.1mg epinephrine in 20mL) injection, USP single dose vial (USA)
Presentation	5x20ml single-use vials (sterile) per box Plain aqueous (colourless) solution	25x20ml single-use vials (sterile) per box Aqueous (clear) solution
Excipients	hydrochloric acid, sodium chloride, sodium hydroxide, sodium metabisulfite	Sodium chloride, citric acid monohydrate, sodium metabisulfite, sodium hydroxide, hydrochloric acid

Storage	<p>XYLOCAINE WITH ADRENALINE in single dose vials should be stored below 25°C.</p> <p>Solutions with adrenaline (epinephrine) acid tartrate should be protected from light.</p>	<p>All solutions should be stored at 20° to 25°C. Protect from light.</p>
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Contraindications

Lidocaine HCl is contraindicated in patients with a known history of hypersensitivity to local anesthetics of the amide type.

Adverse Event Reporting

Reporting any suspected adverse event is important for the continued monitoring of the safety of all medicines. Any adverse events which are experienced with **XYLOCAINE-MPF 2 per cent with epinephrine 1:200,000 (400mg lidocaine hydrochloride and 0.1mg epinephrine in 20mL) injection, USP single dose vial (USA)** should be reported by healthcare professionals and patients to our Medical Information. This information can also be reported to the TGA at <https://www.tga.gov.au/reporting-problems>.

Reach Pharmaceuticals Medical Information can be contacted by phone on 0478 061 879 or via email at medical@reach-pharma.com

For sales related enquiries, please contact us on sales@reach-pharma.com or call 0478 061 879.

We would appreciate if you could distribute this information to those in your organisation who prescribe the product including but not limited to anaesthetists, emergency department physicians and intensive care physicians.

Yours sincerely,

Reach Pharmaceuticals Pty Ltd