



ProPharmaceuticalsGroup

Pro Pharmaceuticals Group Pty LTD

ABN: 20 605 457 430

www.propg.com.au

Dear Healthcare Professional,

Shortage of XYLOCAINE 2% WITH ADRENALINE 1:200,000 20mL injection vial

Pro Pharmaceuticals Group recognises the importance of supplying essential medicines in Australia and would like to advise you the change in supply status of XYLOCAINE 2% WITH ADRENALINE 1:200,000 20mL injection vial in Australia.

The Australian registered medicine, XYLOCAINE 2% WITH ADRENALINE 1:200,000 20mL injection vial AUST R: 12021 Active ingredients: . adrenaline (epinephrine) acid tartrate lidocaine (lignocaine) hydrochloride Dosage form: Injection, solution Sponsor: Aspen Pharmacare Australia Pty Ltd is currently in shortage due to manufacturing issues.

Pro Pharmaceuticals Group has arranged for the supply of an alternative product, **XYLOCAINE 2% with EPINEPHRINE 1:200,000–lidocaine hydrochloride and epinephrine injection USP 20mL single use vial (Aspen Canada)**. This product 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 September 2023** for the following indication(s):

XYLOCAINE solutions are indicated for the production of local or regional anaesthesia by the following techniques: infiltration, intravenous regional anaesthesia - excluding solutions with adrenaline, peripheral nerve block such as intercostal block, major plexus block such as brachial plexus block, epidural block, subarachnoid block.

XYLOCAINE 2% with EPINEPHRINE 1:200000 - lidocaine hydrochloride and epinephrine injection USP 20mL single use vial (Aspen Canada) is registered and marketed in Canada by Aspen

Pro Pharmaceuticals Group recommends that healthcare professionals refer to the Australian approved Product Information for recommended dosing for various indications.

Please note: CONTAINS SULFITES

As outlined in the Canada prescribing information, **Xylocaine 2% with Epinephrine 1:200000 - lidocaine hydrochloride and epinephrine injection USP 20mL single use vial (Aspen Canada)** 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 of **Xylocaine 2% with Epinephrine 1:200000 - lidocaine hydrochloride and epinephrine injection USP 20mL single use vial (Aspen Canada)** is contraindicated in patients with hypersensitivity to sulfite-containing medications.

Reporting suspected adverse events is important for the continued monitoring of the safety of all medicines. Any adverse events which are experienced with XYLOCAINE 2% W EPINEPHRINE 1:200000 SOLUTION (Aspen Canada) must be reported by healthcare professionals, pharmacists, and patients to the TGA at <https://www.tga.gov.au/reporting-problems> or to Pro Pharmaceuticals Group on 1300077674 or email regulatory@propg.com.au

Any product complaints with **XYLOCAINE 2% with EPINEPHRINE 1:200000 – lidocaine hydrochloride and epinephrine injection USP 20mL single use vial (Aspen Canada)** should be reported to Pro Pharmaceuticals Group on 1300 077674 or email regulatory@propg.com.au

For any orders please contact Pro Pharmaceuticals Group on 1300077674 or email info@propg.com.au

Please forward this information to relevant staff members in your organisation.

For further information, please contact Pro Pharmaceuticals Group on 1300077674 or email info@propg.com.au

Sincerely,

Sandip Manku – Director Pro Pharmaceuticals Group