



24th January 2022

Dear Healthcare Professional,

Availability of Xylanaest 1% with Epinephrine 1:200,000 5ml ampoule (Gebro Pharma) - under alternative supply arrangement of Section 19A of the Therapeutic Goods Act.

Due to the shortage of the Australian registered XYLOCAINE 1% WITH ADRENALINE 1:200,000 20mL injection vial, Reach Pharmaceuticals has arranged the supply of an alternative product called **Xylanaest 1% with Epinephrine 1:200,000 5ml ampoule (Gebro Pharma)** registered and marketed in Austria.

Xylanaest 1% with Epinephrine 1:200,000 5ml ampoule (Gebro Pharma) 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 November 2022 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.

The Section 19A product has been approved for use for the same indications as the Australian ARTG registered product. A comparison table of differences between Australian registered product **XYLOCAINE 1% WITH ADRENALINE 1:200,000 20mL injection vial (AUST R 12015)** and the product registered in Austria, **Xylanaest 1% with Epinephrine 1:200,000 5ml ampoule (Gebro Pharma)** is given below

	ARTG product	S19A product
	XYLOCAINE 1% WITH ADRENALINE 1:200,000 20mL injection vial (AUST R 12015)	Xylanaest 1% with Epinephrine 1:200,000 5ml ampoule (Gebro Pharma)
Excipients	hydrochloric acid, sodium chloride, sodium hydroxide, sodium metabisulfite and water for injections.	sodium chloride, sodium hydroxide, sodium metabisulphite and water for injection.
Container and Pack Size	20 mL single dose Vial	In a pack of 5 ampoules of 5 mL. Single use ampoules.
Storage	Store below 25°C.	Store below 25°C. Store in original package to Protect from light.



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Please note: CONTAINS SULFITES

As outlined in the Australia prescribing information, **Xylanaest 1% with Epinephrine 1:200,000 5ml ampoule (Gebro Pharma)** 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 **Xylanaest 1% with Epinephrine 1:200,000 5ml ampoule (Gebro Pharma)** is contraindicated in patients with hypersensitivity to sulfite-containing medications.

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 **Xylanaest 1% with Epinephrine 1:200,000 5ml ampoule (Gebro Pharma)** 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