

11th April 2023

Dear Healthcare Professional,

STEMETIL prochlorperazine mesilate 12.5mg/1mL injection ampoule, AUST R: 27555 - alternative supply arrangement under Section 19A of the *Therapeutic Goods Act*.

Due to the shortage of STEMETIL prochlorperazine mesilate 12.5mg/1mL injection ampoule AUST R: 27555, Reach Pharmaceuticals has arranged the supply of an alternative product called **STEMETIL prochlorperazine mesilate 12.5mg/1mL injection ampoule (Ireland)** registered and marketed in Ireland.

STEMETIL prochlorperazine mesilate 12.5mg/1mL injection ampoule (Ireland) is not registered in Australia and supply is authorised under an approval granted by the Therapeutic Goods Administration (TGA) under Section 19A of the *Therapeutic Goods Act*, 1989 until 30th November 2023 for the following indication(s):

Nausea and vomiting due to various causes including migraine; vertigo due to Meniere's syndrome, labyrinthitis and other causes.

The S19A approved Irish product is identical in active ingredient and strength to the Australian registered product.

Please refer to the Australian Product Information for **STEMETIL prochlorperazine mesilate 12.5mg/1mL injection ampoule, AUST R: 27555** (available at <https://www.ebs.tga.gov.au>) when prescribing and administering **STEMETIL prochlorperazine mesilate 12.5mg/1mL injection ampoule (Ireland)**.

Please note the following similarities and differences between AU registered product STEMETIL prochlorperazine mesilate 12.5mg/1mL injection ampoule (AUST R: 27555) and Irish product STEMETIL prochlorperazine mesilate 12.5mg/1mL injection ampoule (Ireland) to be supplied under section 19A (referred as the S19A product below):

	ARTG product (STEMETIL prochlorperazine mesilate 12.5mg/1mL injection ampoule AUST R: 27555)	S19A product (STEMETIL prochlorperazine mesilate 12.5mg/1mL solution for injection ampoule (Ireland))
Excipients	<ul style="list-style-type: none"> • monoethanolamine • sodium chloride • sodium metabisulfite • sodium sulfite • water for injections 	Anhydrous Sodium sulphite (E221) Sodium metabisulphite (E223) Sodium chloride Ethanolamine Water for injections
Storage	Store below 25°C. Protect from Light. Keep ampoules and trays in the carton until time of use.	Do not store above 25°C. Keep ampoule in the outer carton. After opening the ampoule, the solution should be used immediately. Any solution remaining should be discarded. Discoloured solution should not be used.

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 **STEMETIL prochlorperazine mesilate 12.5mg/1mL injection ampoule (Ireland)** 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 **1800 505 306** or via email at medical@reach-pharma.com

For sales related enquiries, please contact us on sales@reach-pharma.com or call 0422 429 648.

We would appreciate if you could distribute this information to those in your organisation who prescribe the product.

Yours sincerely,

Reach Pharmaceuticals Pty Ltd