17 January 2024

Shortage of PROCALM prochlorperazine maleate 5 mg tablet blister pack (AUST R 158415) and alternative supply arrangement under Section 19A of the *Therapeutic Goods Act 1989*

Dear Healthcare Professional,

Due to the shortage of **PROCALM prochlorperazine maleate 5 mg tablet blister pack (AUST R 158415),** ORSPEC Pharma has arranged the supply of an alternative product on a temporary basis.

Stemetil prochlorperazine maleate 5mg tablets (Ireland) are 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 **30 June 2024.**

Stemetil prochlorperazine maleate 5mg tablets (Ireland) are approved for use under Section 19A of the *Therapeutic Goods Act 1989* for the following indications:

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

Please note: CONTAINS LACTOSE

Stemetil prochlorperazine maleate 5mg tablets (Ireland) should not be used in patients allergic to lactose.

Prior to dispensing and administration, healthcare professionals should determine if this product is suitable for the patient.

The section 19A approved product is identical in active ingredient, strength and dose form to the Australian registered product.
Please note the differences between **PROCALM prochlorperazine maleate 5 mg tablet blister pack (AUST R 158415)** and **Stemetil prochlorperazine maleate 5mg tablets (Ireland):**

	ARTG product PROCALM prochlorperazine maleate 5 mg tablet blister pack (AUST R 158415)	**Section 19A product** Stemetil prochlorperazine maleate 5mg tablets (Ireland)
Pack Presentation	Blister packs of 25 tablets	Bottles of 250 tablets
Excipients	Lactose monohydrate Maize starch Purified water Colloidal anhydrous silica Magnesium stearate	Lactose monohydrate Maize starch Colloidal anhydrous silica Magnesium stearate
Storage	Store below 25°C and protect from light.	Do not store above 30°C. Store in the original container.

Stemetil prochlorperazine maleate 5mg tablets (Ireland) are registered in Ireland and are packaged in English.
Patients should be advised to disregard the patient information leaflet for **Stemetil prochlorperazine maleate 5mg tablets (Ireland).**
For prescribing and dosing information, please refer to the Australian Product Information for **PROCALM prochlorperazine maleate 5 mg tablet blister pack (AUST R 158415)** available at https://www.ebs.tga.gov.au/

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 maleate 5mg tablets (Ireland),** should be reported by healthcare professionals and patients to ORSPEC Pharma on 024 339 4239 or email at customerservice@orspecpharma.com. Alternatively, this information can be reported to the TGA at https://www.tga.gov.au/reporting-problems

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

For further information, please contact ORSPEC Pharma on 024 339 4239 or email customerservice@orspecpharma.com.

Yours sincerely,

Deon Scheepers
Managing Director
ORSPEC Pharma