29th September 2023

Shortage of NORIMIN-1 28 day tablet blister pack and alternative supply arrangement under Section 19A of the *Therapeutic Goods Act, 1989*

Dear Healthcare Professional,

This communication is sent by ORSPEC Pharma to notify your organisation that due to the shortage of **NORIMIN-1 28 day tablet blister pack (AUST R: 62136)** ORSPEC Pharma has arranged the supply of an alternative product on a temporary basis.

Norimin norethisterone 1mg and ethinylestradiol 0.035mg tablet blister pack (UK), is NOT registered in Australia and supply is granted under an exemption granted by the Therapeutic Goods Administration (TGA) under Section 19A of the *Therapeutic Goods Act, 1989* until **31 March 2024.**

Norimin norethisterone 1mg and ethinylestradiol 0.035mg tablet blister pack (UK) is approved for use under Section 19A for *Oral contraception.*

ORSPEC Pharma recommends that healthcare professionals refer to the Australian Product Information available at https://www.ebs.tga.gov.au/.

Please note: The section 19A approved product does not contain inactive (placebo) tablets. Pharmacists should ensure that patients are aware of this difference and understand the different dosing instructions.

The s19A approved UK product is identical in active ingredient and strength to the Australian registered product. The differences between the products are noted below:

	ARTG product NORIMIN-1 28 day tablet blister pack (AUST R: 62136)	**S19A product** Norimin norethisterone 1mg and ethinylestradiol 0.035mg tablet blister pack (UK)
Presentation	Each blister contains 21 white active tablets and 7 orange inactive tablets.	Each blister contains 21 white active tablets. There are no inactive (placebo) tablets).
Excipients	White active tablet Magnesium stearate Povidone Maize starch Lactose monohydrate. Orange placebo tablet Magnesium stearate Lactose	Maize starch Polyvidone Magnesium stearate Lactose monohydrate

	Lactose monohydrate Microcrystalline cellulose Sunset yellow FCF	
Pack size	4 blisters each containing 21 active tablets and 7 placebo tablets	Packs of 1 or 3 blisters each containing 21 active tablets
Dosing	One active tablet is taken daily, following the arrows on the pack, until all 21 active tablets have been taken. The woman should then be instructed to take one orange inactive tablet daily for the next seven days.	One tablet taken at the same time each day from the first day of the menstrual cycle. For subsequent cycles, no tablets are taken for 7 days, then a new course is started of 1 tablet daily for the next 21 days.

Norimin norethisterone 1mg and ethinylestradiol 0.035mg tablet blister pack (UK) is registered in the United Kingdom and is packaged in the English language. For dosing and administration information, please refer to the Australian Product Information for **NORIMIN-1 28 day tablet blister pack (AUST R: 62136)** 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 **Norimin norethisterone 1mg and ethinylestradiol 0.035mg tablet blister pack (UK),** 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 cusromerservice@orspecpharma.com.

Yours sincerely,

Deon Scheepers
Managing Director
ORSPEC Pharma