ProPharmaceuticalsGroup

Pro Pharmaceuticals Group Pty LTD
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Dear Healthcare Professional,

Shortage of RESPRIM FORTE trimethoprim/sulfamethoxazole 160 mg/800 mg tablet blister pack

Pro Pharmaceuticals Group recognises the importance of supplying essential medicines in Australia and would like to advise you of the change in supply status of RESPRIM FORTE trimethoprim/sulfamethoxazole 160 mg/800 mg tablet blister pack in Australia.

The Australian registered medicine, RESPRIM FORTE trimethoprim/sulfamethoxazole 160 mg/800 mg tablet blister pack AUST R: 17682 Sponsored by Alphapharm Pty Ltd is currently in shortage due to manufacturing issues.

Pro Pharmaceuticals Group has arranged for the supply of alternative products, **Sulfamethoxazole and Trimethoprim Tablets, USP 800 mg/160 mg (AUROBINDO) and Sulfamethoxazole and Trimethoprim Tablets, USP 400 mg/80 mg (AUROBINDO)**. These products are 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 **28th February 2023** for the following indication(s):

Upper and lower respiratory tract infections; renal and urinary tract infections; skin and wound infections; septicaemias and other infections caused by sensitive organisms.

Sulfamethoxazole and Trimethoprim Tablets, USP 800 mg/160 mg (AUROBINDO) and Sulfamethoxazole and Trimethoprim Tablets, USP 400 mg/80 mg (AUROBINDO) are registered and marketed in USA by Aurobindo.

Please note the following differences between **RESPRIM FORTE trimethoprim/sulfamethoxazole 160 mg/800 mg tablet blister pack (AUST R: 17682)** and **Sulfamethoxazole and Trimethoprim Tablets, USP 800mg/ 160mg (Aurobindo) and Sulfamethoxazole and Trimethoprim Tablets, USP 400 mg/80 mg (AUROBINDO)** to be supplied under section 19A.

	RESPRIM FORTE trimethoprim/sulfamethoxazole 160 mg/800 mg tablet blister pack (AUST R: 17682)	**Sulfamethoxazole and Trimethoprim Tablets, USP 800mg/ 160mg (Aurobindo) Sulfamethoxazole and Trimethoprim Tablets, USP 400 mg/80 mg (AUROBINDO).** (S19A products)
Excipients	povidone docusate sodium sodium starch glycollate magnesium stearate Excipients with known effect: sulfites	docusate sodium magnesium stearate pregelatinized starch (maize) sodium benzoate sodium starch glycolate
Additional warning		These products contain sodium benzoate. This excipient is not declared on the product labels
Pack Size	blisters of 10 tablets	• bottles of 100 tablets both 800mg/ 160mg & 400 mg/80 mg strengths • bottles of 500 tablets 800mg/ 160mg strength
Storage	Store below 30ºC.	Store at 20º to 25ºC excursions permitted to 15º to 30ºC

Pro Pharmaceuticals Group recommends that healthcare professionals refer to the Australian approved Product Information for recommended dosing for various indications, available at: https://www.ebs.tga.gov.au/

Reporting suspected adverse events is important for the continued monitoring of the safety of all medicines. Any adverse events which are experienced with **Sulfamethoxazole and Trimethoprim Tablets, USP 800 mg/160 mg (AUROBINDO) and Sulfamethoxazole and Trimethoprim Tablets, USP 400 mg/80 mg (AUROBINDO)** 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 for **Sulfamethoxazole and Trimethoprim Tablets, USP 800 mg/160 mg (AUROBINDO) and Sulfamethoxazole and Trimethoprim Tablets, USP 400 mg/80 mg (AUROBINDO)** 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 orders@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