



Pro Pharmaceuticals Group Pty LTD
ABN: 20 605 457 430
www.propg.com.au

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 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 Active ingredients: sulfamethoxazole trimethoprim Dosage form: Tablet, uncoated Sponsor: 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 (Rising Health) and Sulfamethoxazole and Trimethoprim Tablets, USP 400 mg/80 mg (Rising Health)**. 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 (Rising Health) and Sulfamethoxazole and Trimethoprim Tablets, USP 400 mg/80 mg (Rising Health) are registered and marketed in USA by Rising Health.

	RESPRIM FORTE trimethoprim/sulfamethoxazole 160 mg/800 mg tablet blister pack (AUST R: 17682)	Sulfamethoxazole and Trimethoprim Tablets, USP 800mg/ 160mg (Rising Health) Sulfamethoxazole and Trimethoprim Tablets, USP 400 mg/80 mg (Rising Health) (S19A products)
Excipients	povidone docusate sodium sodium starch glycolate 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	<ul style="list-style-type: none"> bottles of 100 tablets both 800mg/ 160mg & 400 mg/80 mg strengths bottles of 500 tablets 800mg/ 160mg strength
Storage	Store below 30°C.	Store at 20° to 25°C excursions permitted to 15° to 30°C

Pro Pharmaceuticals Group recommends that healthcare professionals refer to the Australian approved Product Information for recommended dosing for various indications.

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 (Rising Health) and Sulfamethoxazole and Trimethoprim Tablets, USP 400 mg/80 mg (Rising Health)** 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 with **Sulfamethoxazole and Trimethoprim Tablets, USP 800 mg/160 mg (Rising Health)** and **Sulfamethoxazole and Trimethoprim Tablets, USP 400 mg/80 mg (Rising Health)** 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