Pro Pharmaceuticals Group Pty LTD
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Dear Healthcare Professional,

Shortage of PHENOXYMETHYLPENICILLIN-AFT phenoxymethylpenicillin (as potassium salt) 250mg/5ml powder for oral liquid bottle AUST R: 159754

Pro Pharmaceuticals Group recognises the importance of supplying essential medicines in Australia and would like to advise you the change in supply status of PHENOXYMETHYLPENICILLIN-AFT phenoxymethylpenicillin (as potassium salt) 250mg/5ml powder for oral liquid bottle AUST R: 159754 in Australia.

The Australian registered medicine, PHENOXYMETHYLPENICILLIN-AFT phenoxymethylpenicillin (as potassium salt) 250mg/5ml powder for oral liquid bottle AUST R: 159754 Active ingredients: phenoxymethylpenicillin potassium Dosage form: Oral Liquid, powder for Sponsor: AFT Pharmaceuticals Pty Ltd is currently in shortage due to manufacturing issues.

Pro Pharmaceuticals Group has arranged for the supply of an alternative product, **PENOPEN phenoxymethylpenicillin 250mg/5ml powder for oral solution (Remedica, Cyprus)**. This product is 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 **31st January 2024** for the following indication(s):

When oral therapy is required in the treatment of mild to moderately severe infections due to penicillin sensitive organisms such as penicillin sensitive staphylococci, pneumococci, gonococci and haemolytic streptococci. Therapy should be guided by bacteriological studies, including sensitivity tests, and by clinical response. For prophylactic use in recurrent streptococcal infections including the prevention of recurrence following rheumatic fever and/or Sydenham's chorea. For the prevention of bacterial endocarditis in patients with rheumatic fever and/or congenital heart disease who are about to undergo dental or upper respiratory surgery or instrumentation. Oral penicillin should not be used as adjunctive prophylaxis for genitourinary instrumentation or surgery, lower intestinal tract surgery, sigmoidoscopy or complications of childbirth.

PENOPEN phenoxymethylpenicillin 250mg/5ml powder for oral solution (Remedica, Cyprus) is registered and marketed in Cyprus by Remedica.

The s19A approved Cyprus product is identical in active ingredient and strength to the Australian registered product, with the labelling and package insert in both English and Greek. Pro Pharmaceuticals Group recommends that healthcare professionals refer to the Australian approved Product Information for recommended dosing for various indications. Please refer to the table below for the differences between the products:

	ARTG product PHENOXYMETHYLPENICILLIN-AFT phenoxymethylpenicillin (as potassium salt) 250mg/5ml powder for oral liquid bottle - AUST R: 159754	**S19A product** PENOPEN phenoxymethylpenicillin 250mg/5ml powder for oral solution
Presentation	Pale orange granular powder which when reconstituted with purified water forms oral solution which is a clear orange coloured solution with an orange odour and flavour which contains phenoxymethylpenicillin potassium equivalent to phenoxymethylpenicillin 250 mg/5 mL Supplied in HDPE bottles. 100mL.	White powder which after reconstitution gives an orange, flavoured solution. Each 5 ml contains phenoxymethylpenicillin potassium equivalent to 250 mg phenoxymethylpenicillin. Amber glass bottles with aluminium closure. Pack size of 100 ml solution.
Excipients ** - excipients that are required to be declared on the label of medicines as per*	Sucrose* Sodium benzoate* Sodium saccharin* 175788 Euroblend Orange PI (105922) Trusil Orange Flavour 10814413 PI (106046)	Sodium benzoate E211* Disodium edetate Saccharin sodium* Acesulfam potassium Silica, colloidal anhydrous Sunset yellow FCF E110

Therapeutic Goods Order No. 91 - Schedule 1		Apricot flavour liquid Sucrose* Povidone **Saccharin sodium is NOT declared on the product label.** *Sucrose and sodium benzoate are declared on the product label.*
Reconstitution instructions	250 mg/5 mL: Add 60 mL of purified water and shake well.	Shake to loosen the powder. Add water up to the bottle line, invert the bottle, tap until the powder falls in the water and shake well. Allow the solution to stand for a few seconds and when the solution retreats below the bottle line, add more water up to the bottle line and shake again.
Storage	The unreconstituted powder should be stored below 25 °C. The reconstituted oral liquid should be stored under refrigeration (2 - 8 °C). The product should be protected from light and moisture. Shelf life of reconstituted oral solution: 10 days	Unreconstituted: store below 25 °C. Protect from light and moisture. Store the reconstituted solution up to 14 days in a refrigerator.

Reporting suspected adverse events is important for the continued monitoring of the safety of all medicines. Any adverse events which are experienced with PENOPEN phenoxymethylpenicillin 250mg/5ml powder for oral solution (Remedica, Cyprus) 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 **PENOPEN phenoxymethylpenicillin 250mg/5ml powder for oral solution (Remedica, Cyprus)** 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