



ProPharmaceuticalsGroup

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

Dear Healthcare Professional,

Shortage of AMOXYCILLIN SANDOZ amoxicillin trihydrate 250mg/5mL powder for oral suspension bottle ARTG: 93720

Pro Pharmaceuticals Group recognises the importance of supplying essential medicines in Australia and would like to advise you the change in supply status of AMOXYCILLIN SANDOZ amoxicillin trihydrate 250mg/5mL powder for oral suspension bottle in Australia.

The Australian registered medicine, AMOXYCILLIN SANDOZ amoxicillin trihydrate 250mg/5mL powder for oral suspension bottle ARTG: 93720 is currently in shortage due to manufacturing issues.

Pro Pharmaceuticals Group has arranged for the supply of an alternative product, **AMOXICILLIN 250MG/5ML ORAL SUSPENSION SUGAR FREE BP (ATHLONE)**. 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 **28th February 2023** for the following indication(s):

Treatment of the following infections due to susceptible strains of sensitive organisms:

Note:

Therapy should be guided by bacteriological studies, including sensitivity tests, and by clinical response. Amoxicillin alone or in combination with another antibiotic, may be used in an emergency where the causative has not been identified.

- Respiratory tract infections (acute and chronic): H. influenzae; Streptococcus; S. pneumoniae; Staphylococcus, nonpenicillinase producing; E. coli.
- Urogenital infections (complicated and uncomplicated, acute and chronic): E.coli P.mirabilis and Strep. faecalis.
- Gonorrhoea: N. gonorrhoea (nonpenicillinase producing).
- Skin and skin structure infections: Staphylococcus, nonpenicillinase producing; Streptococcus; E. coli.
- Prophylaxis of endocarditis: Amoxicillin may be used for the prophylaxis of bacterial endocarditis in individuals at particular risk, such as those with a prosthetic heart valve or those who have previously had endocarditis.

AMOXICILLIN 250MG/5ML ORAL SUSPENSION SUGAR FREE BP (ATHLONE) is registered and marketed in the UK by Athlone Laboratories Limited.

The S19A approved UK product is identical in active ingredient and strength to the Australian registered product. A comparison table of differences between excipients is given below:

	AMOXYCILLIN SANDOZ amoxicillin trihydrate 250mg/5mL powder for oral suspension bottle ARTG: 93720	S19A product - AMOXICILLIN 250MG/5ML ORAL SUSPENSION SUGAR FREE BP (ATHLONE)
Excipients	Anhydrous citric acid, sodium benzoate, aspartame, purified talc, sodium citrate anhydrous, guar gum silicon dioxide, lemon flavouring, peach-apricot flavouring, orange flavouring	Sodium Benzoate (E211) Disodium Edetate Sodium Citrate Citric Acid Monohydrate Colloidal Anhydrous Silica Sorbitol Saccharin Sodium Orange Bramble Flavour Quinoline Yellow (E104)

		Xanthan Gum (E415)
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Pro Pharmaceuticals Group recommends that healthcare professionals refer to the Australian approved Product Information for AMOXYCILLIN SANDOZ amoxicillin trihydrate 250mg/5mL powder for oral suspension bottle ARTG: 93720 (available at <https://www.ebs.tga.gov.au/>) 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 **AMOXYCILLIN 250MG/5ML ORAL SUSPENSION SUGAR FREE BP (ATHLONE)** 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 **AMOXYCILLIN 250MG/5ML ORAL SUSPENSION SUGAR FREE BP (ATHLONE)** 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