

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 of the change in supply status of AMOXYCILLIN SANDOZ amoxicillin trihydrate 250mg/5mL powder for oral suspension bottle ARTG: 93720 in Australia.

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

Pro Pharmaceuticals Group has arranged for the supply of an alternative product, **Amoxicillin Powder for Oral Suspension 250mg/5ml (West-Ward)**. 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 **28**th **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 (nonpencillinase 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 Powder for Oral Suspension 250mg/5ml (West-Ward) is registered and marketed in the USA by West-Ward Corp USA. It is identical in active ingredient and strength to the Australian registered product. A comparison table of differences between the products is given below:

Please note: The section 19A approved product contains sodium benzoate and sucrose. These excipients are not declared on the product label. Prior to dispensing, pharmacists should determine if this product is appropriate for the patient.

	ARTG product AMOXYCILLIN SANDOZ amoxicillin trihydrate 250mg/5mL powder for oral suspension bottle ARTG: 93720	S19A Product Amoxicillin Powder for Oral Suspension 250mg/5ml (West-Ward)
Excipients	Anhydrous citric acid, sodium benzoate, aspartame, purified talc, sodium citrate anhydrous, guar gum silicon dioxide, lemon flavouring, peach-apricot flavouring, orange flavouring	silicon dioxide hypromelloses sodium benzoate sucrose trisodium citrate dihydrate xanthan gum tutti frutti flavour

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Storage	Powder: Store below 25 °C. Keep the container tightly closed. After Mixing: Store in a refrigerator (2 °C-8 °C). Discard unused suspension after 14 days.	Any unused portion of the reconstituted
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Pro Pharmaceuticals Group recommends that healthcare professionals refer to the Australian approved Product Information for recommended dosing for various indications. This information can be found here: 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 **Amoxicillin Powder for Oral Suspension 250mg/5ml (West-Ward)** 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 **Amoxicillin Powder for Oral Suspension 250mg/5ml (West-Ward)** 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