

23rd August 2022

Dear Healthcare Professional,

Availability of

**AMOXICILLIN 250MG/5ML ORAL SUSPENSION SUGAR FREE BP (KENT) -
alternative supply arrangement under Section 19A of the *Therapeutic Goods Act*.**

Due to the shortage of the Australian registered AMOXYCILLIN SANDOZ amoxicillin trihydrate 250mg/5mL powder for oral suspension bottle ARTG: 93720, Reach Pharmaceuticals has arranged the supply of an alternative product called **AMOXICILLIN 250MG/5ML ORAL SUSPENSION SUGAR FREE BP (KENT)**, registered and marketed in the United Kingdom.

AMOXICILLIN 250MG/5ML ORAL SUSPENSION SUGAR FREE BP (KENT) 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 February 2023 for the following indications:

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.*

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:



REACH
pharmaceuticals

	AMOXYCILLIN SANDOZ amoxicillin trihydrate 250mg/5mL powder for oral suspension bottle ARTG: 93720	S19A product - AMOXICILLIN 250MG/5ML ORAL SUSPENSION SUGAR FREE BP (KENT)
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)

Please refer to the Australian Product Information for **AMOXYCILLIN SANDOZ amoxicillin trihydrate 250mg/5mL powder for oral suspension bottle ARTG: 93720** (available at <https://www.ebs.tga.gov.au>) when prescribing and administering **AMOXICILLIN 250MG/5ML ORAL SUSPENSION SUGAR FREE BP (KENT)**.

Adverse Event Reporting

Reporting any suspected adverse event is important for the continued monitoring of the safety of all medicines. Any adverse events which are experienced with **AMOXICILLIN 250MG/5ML ORAL SUSPENSION SUGAR FREE BP (KENT)** should be reported by healthcare professionals and patients to our Medical Information. This information can also be reported to the TGA at <https://www.tga.gov.au/reporting-problems>.

Reach Pharmaceuticals Medical Information can be contacted by phone on 1800 505 306 or via email at medical@reach-pharma.com

For sales related enquiries, please contact us on sales@reach-pharma.com or call 0422 429 648.

We would appreciate if you could distribute this information to those in your organisation who prescribe the product.

Yours sincerely,

Reach Pharmaceuticals Pty Ltd