

1st December 2022

Dear Healthcare Professional,

Availability of AMOXICILLIN 125mg/5mL ORAL SUSPENSION SUGAR FREE BP (ATHLONE) - alternative supply arrangement under Section 19A of the *Therapeutic Goods Act*.

Due to the shortage of the Australian registered APO-AMOXICILLIN amoxicillin (as trihydrate) 125mg/5mL powder for suspension bottle AUST R: 137882, Reach Pharmaceuticals has arranged the supply of an alternative product called **AMOXICILLIN 125mg/5mL ORAL SUSPENSION SUGAR FREE BP (ATHLONE)**, registered and marketed in the United Kingdom.

AMOXICILLIN 125mg/5mL ORAL SUSPENSION SUGAR FREE BP (ATHLONE) 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 30th June 2023 for the following indications:

It is indicated for the 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. However, in emergency cases where the causative organism has not been identified, therapy with amoxicillin may be useful. Clinical judgment will decide whether combination with another antibiotic would provide a sufficiently broad spectrum of activity pending sensitivity test results

Skin and skin structure

Staphylococcus, non-penicillinase producing; Streptococcus; E. coli.

Respiratory (acute and chronic)

H. influenzae; Streptococcus; Strep. pneumoniae; Staphylococcus, non-penicillinase producing; E. coli.

Genitourinary tract (complicated and uncomplicated, acute and chronic)

E. coli, P. mirabilis and Strep. faecalis.

Gonorrhoea

N. gonorrhoeae (non-penicillinase producing).

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

	ARTG product APO-AMOXYCILLIN amoxicillin (as trihydrate) 125mg/5mL powder for suspension bottle AUST R: 137882	S19A product AMOXYCILLIN 125mg/5mL ORAL SUSPENSION SUGAR FREE BP (ATHOLNE)
Excipients	colloidal anhydrous silica Flavour saccharin sodium sodium citrate dihydrate sorbitol sunset yellow FCF xanthan gum	Sodium Benzoate (E211) Disodium Edetate Sodium Citrate Citric Acid Monohydrate Colloidal Anhydrous Silica Sorbitol (E420) Saccharin Sodium Orange Bramble Flavour Quinoline Yellow (E104) Xanthan Gum (E415)
Additional warnings		This product contains sodium benzoate and saccharin . These excipients are not declared on the product label.

Please refer to the Australian Product Information for **APO-AMOXYCILLIN amoxicillin (as trihydrate) 125mg/5mL powder for suspension bottle AUST R: 137882** (available at <https://www.ebs.tga.gov.au>) when prescribing and administering **AMOXYCILLIN 125mg/5mL ORAL SUSPENSION SUGAR FREE BP (ATHLONE)**.

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 **AMOXYCILLIN 125mg/5mL ORAL SUSPENSION SUGAR FREE BP (ATHLONE)** 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