

25th November 2022



RE: Shortage of APO-AMOXICILLIN amoxicillin (as trihydrate) 125mg/5mL and 250mg/5mL powder for suspension bottle and alternative supply arrangement under Section 19A of the *Therapeutic Goods Act*.

PO Box 718
Mona Vale
NSW 1660
Australia

+61 2 8401 9777
+61 2 8401 9788
info@linkhealthcare.com.au

Dear Healthcare Professional,

This notification is sent by LINK to inform your organisation that due to the shortage of Australian registered **APO-AMOXICILLIN amoxicillin (as trihydrate) 125mg/5mL and 250mg/5mL powder for suspension bottle (AUST R 137882 & 137883)**, LINK has arranged the supply of an alternative product, **Amoxicillin 125mg/5mL and 250mg/5ml Powder for Oral Suspension Sugar Free (Flamingo Pharma)** registered and marketed in the *United Kingdom*.

Amoxicillin 125mg/5mL and 250mg/5ml Powder for Oral Suspension Sugar Free (Flamingo Pharma) 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 **30 June 2023**.

Amoxicillin 125mg/5mL and 250mg/5ml Powder for Oral Suspension Sugar Free (Flamingo Pharma) is indicated for:

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, nonpenicillinase producing; Streptococcus; E. coli.*
- **Respiratory tract (acute and chronic):** *H. influenzae; Streptococcus; S. pneumoniae; Staphylococcus, nonpenicillinase producing; E. coli.*
- **Genitourinary tract (complicated and uncomplicated, acute and chronic):** *E.coli P.mirabilis and Strep. faecalis.*
- **Gonorrhoea:** *N. gonorrhoea (nonpenicillinase 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. Please note the differences between the products as displayed in the table below.

	ARTG product APO-AMOXICILLIN amoxicillin (as trihydrate) 125mg/5mL and 250mg/5mL powder for suspension bottle (AUST R 137882 & 137883)	S19a Approved UK Product Amoxicillin 125mg/5mL and 250mg/5ml Powder for Oral Suspension Sugar Free (Flamingo Pharma)
Excipients	<ul style="list-style-type: none">• Saccharin sodium• Colloidal silica anhydrous• Sodium citrate dihydrate• Sorbitol• Sunset yellow FCF• Xanthan gum• Tutti Frutti flavor (PI 183)	<ul style="list-style-type: none">• Sodium Benzoate• Disodium Edetate• Sodium Citrate• Citric Acid• Colloidal Anhydrous Silica• Sorbitol

		<ul style="list-style-type: none"> • Saccharin Sodium • Banana Flavour • Quinoline Yellow, E104 • Xanthan Gum
Reconstitution	125mg/5mL and 250mg/5mL - Add 85 mL of water in two portions to dry mixture in the bottle. Shake well after each addition	125mg/5mL add 84ml of potable water 250mg/5mL - add 82ml of potable water Shake until all contents are dispersed
Storage	Powder: Store below 25°C. Protect from moisture. After mixing: store at 2 - 8°C in a refrigerator. Do not freeze. Unused suspension must be discarded after 14 days.	Do not store above 25°C. Any unused portion of the reconstituted suspension must be discarded after 7 days after reconstitution.

Please refer to the Australian Product Information for **APO-AMOXYCILLIN amoxicillin (as trihydrate) 125mg/5mL and 250mg/5mL powder for suspension bottle (AUST R 137882 & 137883)** (available at <https://www.ebs.tga.gov.au>) when prescribing and administering **Amoxicillin 125mg/5mL and 250mg/5ml Powder for Oral Suspension Sugar Free (Flamingo Pharma)**.

Amoxicillin 125mg/5mL and 250mg/5ml Powder for Oral Suspension Sugar Free (Flamingo Pharma) is registered in **the United Kingdom** with the outer package and package insert both in *English*. The active ingredient, strength and dosage form included on the bottle label are in *English*.

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 125mg/5mL and 250mg/5ml Powder for Oral Suspension Sugar Free (Flamingo Pharma)** should be reported by healthcare professionals and patients to Link Healthcare Medical Information. This information can also be reported to the TGA at <https://www.tga.gov.au/reporting-problems>.

Link Healthcare Medical Information can be contacted by phone on 1800 181 060 or via email at medinfo@linkhealthcare.com.au.

Link Healthcare Customer Service contact details

Link Healthcare Customer Service can be contacted via phone on 1800 181 060 or via email at customerservice@linkhealthcare.com.au.

Please contact Link Healthcare Customer Service for further information.

We would appreciate if you could distribute this information to those in your organisation who would be affected by the shortage of the Australian registered **APO-AMOXYCILLIN amoxicillin (as trihydrate) 125mg/5mL and 250mg/5mL powder for suspension bottle (AUST R 137882 & 137883)**.

Yours sincerely,



Charlotte Griffin
Medicine Access Associate