

8th November 2022

RE: Shortage of ALPHAMOX 250mg and 500mg amoxicillin (as trihydrate) capsule blister pack and alternative supply arrangement under Section 19A of the *Therapeutic Goods Act*.

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Dear Healthcare Professional,

This notification is sent by LINK to inform your organisation that due to the shortage of Australian registered **ALPHAMOX 250mg and 500mg amoxicillin (as trihydrate) capsule blister pack**, LINK has arranged the supply of an alternative product, **AMOXICILLIN 250mg and 500mg CAPSULES BP (Athlone)** registered and marketed in the *United Kingdom*.

AMOXICILLIN 250mg and 500mg CAPSULES 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 **28 February 2023**.

AMOXICILLIN 250mg and 500mg CAPSULES BP (Athlone) are indicated for treatment 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 S. 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. Please note the differences in excipient ingredients as displayed in the table below.

	ALPHAMOX 250mg & 500mg amoxicillin (as trihydrate) capsule blister pack (AUST R: 17678 & 17679)	AMOXICILLIN 250mg and 500mg CAPSULES BP (Athlone) (PL 06453/0017 and PL 06453/0018)
Excipients	<ul style="list-style-type: none"> purified talc magnesium stearate sodium starch glycollate colloidal anhydrous silica sodium lauryl sulfate gelatin titanium dioxide brilliant blue FCF iron oxide yellow 	<ul style="list-style-type: none"> Magnesium stearate Ph. Eur. Maize starch Ph. Eur. Capsule shell Erythrosin E127 Quinoline yellow E104 Titanium dioxide E171 Red iron oxide E172 Gelatin NF

	<ul style="list-style-type: none">• microcrystalline cellulose (250mg capsule only)	
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Please refer to the Australian Product Information for **ALPHAMOX 250mg and 500mg amoxicillin (as trihydrate) capsule blister pack** (available at <https://www.ebs.tga.gov.au>) when prescribing and administering **AMOXICILLIN 250mg and 500mg CAPSULES BP (Athlone)**.

AMOXICILLIN 250mg and 500mg CAPSULES BP (Athlone) are 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 pack 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 250mg and 500mg CAPSULES BP (Athlone)** 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 **ALPHAMOX 250mg and 500mg amoxicillin (as trihydrate) capsule blister pack**.

Yours sincerely,



Charlotte Griffin

Medicine Access Associate