15th September 2022

LINK
A CLINIGEN COMPANY

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RE: Shortage of AMCLAVOX DUO FORTE 875/125, amoxicillin (as trihydrate) 875 mg and clavulanic acid (as potassium) 125 mg tablets blister pack and alternative supply arrangement under Section 19A of the *Therapeutic Goods Act*.

Dear Healthcare Professional,

This notification is sent by LINK to inform your organisation that due to the shortage of Australian registered **AMCLAVOX DUO FORTE 875/125, amoxicillin (as trihydrate) 875 mg and clavulanic acid (as potassium) 125 mg tablets blister pack AUST R: 288119**, LINK has arranged the supply of an alternative product, ***Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Aurobindo)*** registered and marketed in *the United States of America.*

Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Aurobindo) 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 **31 January 2023.**

Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Aurobindo) *are indicated for short term treatment of bacterial infections at the following sites when caused by sensitive organisms:*
• Urinary Tract Infections (complicated and uncomplicated)
• Lower Respiratory Tract Infections, including community acquired pneumonia and acute exacerbations of chronic bronchitis.
• Upper Respiratory Tract Infections, such as sinusitis, otitis media and recurrent tonsillitis.
• Skin and Skin Structure infections.
Appropriate culture and susceptibility studies should be performed to identify the causative organism(s) and determine its (their) susceptibility
to amoxicillin and clavulanic acid tablets. However, when there is reason to believe an infection may involve any of the β-lactamase producing
organisms listed above, therapy may be instituted prior to obtaining the results from bacteriological and susceptibility studies. Once these results
are known, therapy should be adjusted if appropriate.
The treatment of mixed infections caused by amoxicillin susceptible organisms and β-lactamase producing organisms susceptible to amoxicillin
and clavulanic acid tablets preparations should not require the addition of another antibiotic due to the amoxicillin content of these products

The s19A approved *American* product is identical in active ingredient and strength to the Australian registered product. Please note table below comparing some differences between the two products.

	Australian registered product **AMCLAVOX DUO FORTE 875/125, amoxicillin (as trihydrate) 875 mg and clavulanic acid (as potassium) 125 mg tablets blister pack AUST R: 288119**	***S19a Approved product*** **Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Aurobindo)**
Active ingredient naming	Amoxicillin (as trihydrate) Clavulanic acid (as potassium)	Amoxicillin (as trihydrate) Clavulanate potassium
Excipient ingredients	Microcrystalline cellulose Magnesium stearate Sodium starch glycollate	Microcrystalline cellulose Magnesium stearate Sodium starch glycollate

	Colloidal anhydrous silica Hypromellose Titanium dioxide Propylene glycol Purified talc Ethylcellulose	Silicon dioxide (Colloidal hydrated silica) Hypromellose Titanium dioxide Polyethylene glycol - Ethylcellulose Crospovidone
Pack size	Blister strip of 10 tablets	Bottles of 100 tablets
Storage	Store below 25 degrees Celsius	Store at 20° to 25°C (68° to 77°F)

Please refer to the Australian Product Information for **AMCLAVOX DUO FORTE 875/125, amoxicillin (as trihydrate) 875 mg and clavulanic acid (as potassium) 125 mg tablets blister pack AUST R: 288119** (available at https://www.ebs.tga.gov.au) when prescribing and administering ***Amoxicillin and clavulanate potassium tablets,USP 875 mg/125 mg (Aurobindo).***

Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Aurobindo) are registered in ***the United States of America*** with the outer package and package insert in both 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 and clavulanate potassium tablets, USP 875 mg/125 mg (Aurobindo)*** 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 **AMCLAVOX DUO FORTE 875/125, amoxicillin (as trihydrate) 875 mg and clavulanic acid (as potassium) 125 mg tablets blister pack AUST R: 288119.**

Yours sincerely,

C Griffin

Charlotte Griffin
Medicine Access Associate