

MEDICATION SAFETY COMMUNICATION

Information for health professionals in NSW public health organisations

Amoxicillin plus clavulanic acid tablets – 19 October 2022 (UPDATED)	
Details of affected product(s)	Amoxicillin 875 mg (as trihydrate) plus clavulanic acid 125 mg (as potassium) tablets <ul style="list-style-type: none">• ALPHACLAV DUO FORTE 875/125– ARTG 230396• AMCLAVOX DUO FORTE 875/125 – ARTG 288119• AMOXYCLAV GENERICHEALTH 875/125 – ARTG 255076• APX-AMOXICILLIN/CLAVULANIC ACID 875/125 – ARTG 351833• AUGMENTIN DUO FORTE– ARTG 54900
Reason for communication	Disruption to supply of multiple brands due to manufacturing constraints and unexpected increase in consumer demand. Medication Safety Communication has been UPDATED to include information about further section 19A alternatives.
Date issue made apparent	17 August 2022
Supply impact dates	Varies dependant on brand – supply anticipated to return to normal by December 2022

Main therapeutic applications

β-lactam antibiotic combined with a β-lactamase inhibitor – broad spectrum of antimicrobial activity. Used to treat a wide range of infections caused by susceptible bacteria.

Alternative agents

Alternative products have been approved for supply under an exemption granted by the Therapeutic Goods Administration (TGA) under [section 19A](#) of the Therapeutic Goods Act 1989.

As of 19 October 2022, the Section 19A alternatives available are Amoxicillin and Clavulanate Potassium Tablets, 875 mg/125 mg (Aurobindo brand from the US):

- in packs of 20 accessible through Medsurge Health
- in packs of 100 accessible through Link Healthcare.

The US alternatives are available under section 19A until 31 January 2023. For further information, please review the US Product Information available [here](#). Further section 19A alternatives may be approved. For the most up-to-date information, please review the [TGA Section 19A approvals register](#). Alternatives may also be available via the TGA's Special Access Scheme, contact regular suppliers for further information.

Alternative antimicrobial agents may also be indicated dependant on factors including, but not limited to, suspected or proven causative bacteria, and site of infection. Clinicians should refer to the *Therapeutic Guidelines: Antibiotic* (accessible via [CIAP](#)), locally produced guidelines and the local Antimicrobial Stewardship policy for guidance. The Infectious Diseases or Antimicrobial Stewardship service can also be contacted for advice on appropriate choice of antimicrobial agents. The National Centre for Antimicrobial Stewardship has produced a Medication Shortage Fact Sheet regarding this disruption to supply – it is accessible [here](#).

Precautions, safety issues and other considerations

- The S19A alternatives differ from the Australian registered products in the following ways –
 - They are presented in bottles of 20 or 100 tablets (compared to blister packs of 10 tablets). The product should be dispensed in tightly closed, moisture-proof containers. Advise patients to keep tablets in the container provided.
 - The generic name of the medicine contains 'clavulanate potassium' – which is the potassium salt of clavulanic acid. The Australian registered products also contain clavulanic acid in the potassium salt form however it is referred to as 'clavulanic acid (as potassium)'.
- Alternative supply arrangements under S19A may not meet demand for this medicine. Local Antimicrobial Stewardship (AMS) programs should consider the appropriateness of the current restrictions on amoxicillin plus clavulanic acid use in their facilities given the disruption to supply.
- Clinicians to be reminded that amoxicillin plus clavulanic acid is not always the most appropriate choice for de-escalation of intravenous antimicrobial therapy (for example, in pneumonia – see [Therapeutic Guidelines: Antibiotic](#) for further information).

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Impacts of this communication on clinical practice

Actions to address the disruption to supply of amoxicillin plus clavulanic acid tablets should be coordinated and implemented by the local Drug and Therapeutics and Antimicrobial Stewardship Committees.

Associated regulatory or policy references

[PD2022_032 Medication Handling](#)

Key contacts

Clinical Excellence Commission (Medication Safety) – CEC-MedicationSafety@health.nsw.gov.au
HealthShare NSW (Category Manager – Strategic Procurement) – Noman.Masood@health.nsw.gov.au