

MEDICATION SAFETY COMMUNICATION

Information for health professionals in NSW public health organisations

Metronidazole tablets (all strengths) – 19 October 2022 (UPDATED)	
Details of affected product(s)	<i>Subject to disruption to supply</i> METROGYL 200 metronidazole 200 mg tablet bottle – ARTG 17654 METROGYL 400 metronidazole 400 mg tablet bottle – ARTG 17655 FLAGYL metronidazole 400 mg tablet blister pack – ARTG 160174 <i>Subject to discontinuation</i> FLAGYL metronidazole 200 mg tablet blister pack – ARTG 160171 METRONIDE 200 metronidazole 200 mg tablet blister pack – ARTG 160173 METRONIDE 400 metronidazole 400 mg tablet blister pack – ARTG 160175
Reason for communication	Disruption to supply due to manufacturing issues, unexpected increases in demand and discontinuation of multiple products. Medication Safety Communication has been UPDATED to include information about further section 19A alternatives.
Date issue made apparent	August 2022
Estimated resolution date	End of November 2022

Main therapeutic applications

Antimicrobial agent indicated for the treatment of anaerobic infections.

Alternative agents

Intermittent supply of the Australian registered metronidazole products may be available from regular wholesalers. Both Flagyl® and MetrogyL® 400 mg tablets are scored and can be cut in half to achieve a 200 mg dose.

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 Wednesday 19 October, the available section 19A alternatives are:

- Metronidazole 200 mg tablets (Crescent Pharma/Actavis brand from the UK) available through Link Healthcare until **31 January 2023**.
- Metronidazole 400 mg tablets (Crescent Pharma/Actavis brand from the UK) are available through Link Healthcare and Medsurge until **31 January 2023**.

These alternative products are identical in active ingredient and strengths to the Australian registered products. Both the 200 mg and 400 mg tablets are presented in a blister pack of 21 tablets Further section 19A alternatives may be approved. For the most up-to-date information, please refer to the [TGA Section 19A approvals register](#).

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 and safety issues associated with alternative products

- The Product Information for the section 19A alternative specifies that the product cannot be stored above 25°C.
- The section 19A alternative contains different excipients (including lactose) to the Australian registered products. Refer to the Dear Health Care Professional letter for the [200 mg](#) and [400 mg](#) products for further information.
- 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 metronidazole use in their facilities given the disruption to supply.

Impacts of this communication on clinical practice

Actions to address the disruption to the supply of metronidazole tablets should be planned and implemented at a local level by the Drug and Therapeutics and Antimicrobial Stewardship Committees.

Associated regulatory or policy issues

[PD2022_032 Medication Handling](#)

Key contacts

Clinical Excellence Commission (Medication Safety) – CEC-MedicationSafety@health.nsw.gov.au
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