

31 January 2023



RE: Shortage of METROGYL 400 metronidazole 400 mg tablet bottle band alternative supply arrangement under Section 19A of the Therapeutic Goods Act.

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Australia

Dear Healthcare Professional,

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This notification is sent by LINK to inform your organisation that due to the shortage of Australian registered **METROGYL 400 metronidazole 400mg tablet bottle (AUST R: 17655)**, LINK has arranged the supply of an alternative product, **Metronidazole 400mg tablets (Crescent Pharma)** registered and marketed in the *United Kingdom*.

Metronidazole 400mg tablets (Crescent Pharma) are 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**

Metronidazole 400mg tablets (Crescent Pharma) are indicated for:

Treatment of infections in which anaerobic bacteria have been identified or are suspected as pathogens, particularly Bacteroides fragilis and other species of bacteroides, and other species such as fusobacteria, eubacteria, clostridia and anaerobic streptococci. Flagyl has been used successfully in septicaemia; bacteraemia; brain abscess; necrotising pneumonia; osteomyelitis; puerperal sepsis; pelvic abscess; pelvic cellulitis; postoperative wound infections.

Metronidazole may be used prophylactically to prevent infection of the surgical site which may have been contaminated or potentially contaminated with anaerobic organisms. Procedures in which this may be assumed to have happened include appendicectomy, colonic surgery, vaginal hysterectomy, abdominal surgery in the presence of anaerobes in the peritoneal cavity and surgery performed in the presence of anaerobic septicaemia.

Note: Metronidazole is inactive against aerobic and facultative anaerobic bacteria.

Oral treatment of urogenital trichomoniasis in the female (trichomonal vaginitis) and in the male, and for the treatment of bacterial vaginosis. The male consort of females suffering from urogenital trichomoniasis should be treated concurrently; all forms of amoebiasis (intestinal and extraintestinal disease and that of symptomless cyst passers); giardiasis; acute ulcerative gingivitis.

The s19A approved United Kingdom product is identical in active ingredient and strength to the Australian registered product, **FLAGYL metronidazole 400 mg tablet blister pack (AUST R 160174)**. The two products differ in their excipient ingredients and storage conditions. These differences are noted below:

	FLAGYL metronidazole 400 mg tablet blister pack (AUST R 160174)	Metronidazole 400mg tablets (Crescent Pharma) (PL 20416/0106)
Excipients	<ul style="list-style-type: none">• Maize starch• Calcium hydrogen phosphate• Povidone• Hypromellose• Magnesium stearate• Macrogol 400• Purified talc (400mg tab only)	<ul style="list-style-type: none">• Lactose• Microcrystalline cellulose• Pregelatinised starch• Magnesium stearate• Quinoline Yellow Aluminium Lake E104• Sunset Yellow Aluminium Lake E110
Storage conditions	Store below 30°C	Do not store above 25°C

Healthcare professionals should advise patients upon dispensing that *Metronidazole 400mg tablets (Crescent Pharma)* contains lactose. **This information is displayed on the pack label.**

Please refer to the Australian Product Information for **FLAGYL metronidazole 400 mg tablet blister pack (AUST R 160174)** (available at <https://www.ebs.tga.gov.au>) when prescribing and administering **Metronidazole 400mg tablets (Crescent Pharma)**.

Metronidazole 400mg tablets (Crescent Pharma) 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 blister strip 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 **Metronidazole 400mg tablets (Crescent 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 **METROGYL 400 metronidazole 400mg tablet bottle (AUST R: 17655)**.

Yours sincerely,

Anita Sharma

Anita Sharma
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Link Medical Product Pty Ltd