

1st March 2023

Dear Healthcare Professional,

Availability of METRONIDAZOLE 200MG/5ML ORAL SUSPENSION (ROSEMONT) alternative supply arrangement under Section 19A of the *Therapeutic Goods Act*.

Due to the shortage of the Australian registered FLAGYL S (metronidazole benzoate) ORAL SUSPENSION ARTG: 27501, Reach Pharmaceuticals has arranged the supply of an alternative product called METRONIDAZOLE 200MG/5ML ORAL SUSPENSION (ROSEMONT), registered and marketed in the United Kingdom.

METRONIDAZOLE 200MG/5ML ORAL SUSPENSION (ROSEMONT) 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 31st May 2023 for the following indications:

Anaerobic Infections: *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. Metronidazole has been used successfully in septicaemia; bacteraemia; brain abscess; necrotising pneumonia; osteomyelitis; puerperal sepsis; pelvic abscess; pelvic cellulitis; postoperative wound infections.*

Notes: a) *Because of the slow absorption and delayed peak plasma level, Flagyl S suspension is not recommended for use in the acute situation.*

b) *Metronidazole is inactive against aerobic and facultative anaerobic bacteria.*

Other Indications: *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 (and extraintestinal disease and that of symptomless cyst passers); giardiasis; acute ulcerative gingivitis.*

The S19A approved UK product is identical in active ingredient and strength to the Australian registered product. A comparison table of differences between the products is given below:

	FLAGYL S benzoyl metronidazole 64 mg/mL suspension oral liquid bottle (AUST R 27501)	S19A product Metronidazole 200mg/5ml Oral Suspension (Rosemont)
Excipients	<ul style="list-style-type: none"> • aluminium magnesium silicate • ethanol • methyl hydroxybenzoate • monobasic sodium phosphate • natural soluble lemon flavour • orange oil terpeneless • propyl hydroxybenzoate 	<ul style="list-style-type: none"> • Dispersible cellulose • colloidal silicon dioxide • sucrose • glucose • sorbitol solution • glycerine • Polysorbate 80



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	<ul style="list-style-type: none">• sucrose	<ul style="list-style-type: none">• methyl hydroxybenzoate• ethyl hydroxybenzoate• propyl hydroxybenzoate• propylene glycol• lemon flavour• orange flavour• purified water
Additional Warnings		<p>This medicine contains 31.1 mg propylene glycol in each ml. Co-administration with any substrate for alcohol dehydrogenase (such as ethanol) may induce adverse effects in children less than 5 years old.</p> <p>Products containing sorbitol may have a laxative effect or cause diarrhoea</p>

Please refer to the Australian Product Information for FLAGYL S (metronidazole benzoate) ORAL SUSPENSION ARTG: 27501 (available at <https://www.ebs.tga.gov.au>) when prescribing and administering **METRONIDAZOLE 200MG/5ML ORAL SUSPENSION (ROSEMONT)**.

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 200MG/5ML ORAL SUSPENSION (ROSEMONT)** should be reported by healthcare professionals and patients to our Medical Information. This information can also be reported to the TGA at <https://www.tga.gov.au/reporting-problems>.

Reach Pharmaceuticals Medical Information can be contacted by phone on 1800 505 306 or via email at medical@reach-pharma.com

For sales related enquiries, please contact us on sales@reach-pharma.com or call 0422 429 648.

We would appreciate if you could distribute this information to those in your organisation who prescribe the product.

Yours sincerely,

Reach Pharmaceuticals Pty Ltd