

27 Jan 2022



RE: Shortage of SULFAMETHOXAZOLE 400 MG AND TRIMETHOPRIM 80 MG CONCENTRATE INJECTION ampoule and alternative supply arrangement under Section 19A of the Therapeutic Goods Act

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Dear Healthcare Professional,

This notification is sent by LINK to inform your organisation that due to a shortage of the Australian registered **DBL™ SULFAMETHOXAZOLE 400 MG AND TRIMETHOPRIM 80 MG CONCENTRATE INJECTION BP, 5mL ampoules (AUST R 16293)**, LINK has arranged the supply of an alternative product. LINK can supply **Co-Trimoxazole 16 mg/80 mg per mL for Infusion (80 mg trimethoprim/400 mg sulfamethoxazole per 5 mL ampoules)**, registered and marketed in the United Kingdom.

Co-Trimoxazole 16 mg/80 mg per mL for Infusion are NOT registered in Australia and supply is granted under an exemption granted by the Therapeutic Goods Administration (TGA) under Section 19A of the Therapeutic Goods Act, 1989 until 30 April 2022

Co-Trimoxazole 16 mg/80 mg per mL for Infusion are approved for use under Section 19A for the following indications:

'Parenteral administration of Sulfamethoxazole 400 mg and Trimethoprim 80 mg Concentrate Injection is indicated where oral dosage is not desirable or practical, e.g. pre- and post-operative infections associated with surgery, trauma or gynaecology; septicaemia and other infections due to sensitive organisms such as typhoid and paratyphoid.'

Co-Trimoxazole 16 mg/80 mg per mL for Infusion are registered in the United Kingdom and are packaged in the English language. Please note that **Co-Trimoxazole 16 mg/80 mg per mL for Infusion** is indicated for use in children from 6 weeks old. This is different to DBL™ SULFAMETHOXAZOLE 400 MG AND TRIMETHOPRIM 80 MG CONCENTRATE INJECTION BP, 5mL ampoules (AUST R 16293), which is indicated for use in children from 8 weeks (2 months) old.

Please refer to the Australian Product Information (PI) for recommended dosing for the above indications, available from <https://www.ebs.tga.gov.au/>.

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 **Co-Trimoxazole 16 mg/80 mg per mL for Infusion** 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.

For further information please contact Link Healthcare Customer Service on **1800 181 060** or via email at customerservice@linkhealthcare.com.au.

We would appreciate if you could distribute this information to those in your organisation who would be affected by the shortage of sulfamethoxazole and trimethoprim injection.

Yours sincerely,

A. Sharma

Anita Sharma

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Link Medical Products Pty Ltd