

11 May 2022



**RE: Shortage of SEPTRIN sugar-free oral liquid, trimethoprim 40 mg/5 mL and sulfamethoxazole 200 mg/5 mL, 100 mL bottle 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 the shortage of Australian registered **SEPTRIN sugar-free oral liquid, trimethoprim 40 mg/5 mL and sulfamethoxazole 200 mg/5 mL, 100 mL bottle (AUST R 11000)**, LINK has arranged the supply of an alternative product, **Co-Trimoxazole 40 mg/200 mg per 5 ml Paediatric Suspension (Aspen)** registered and marketed in the *United Kingdom*.

**Co-Trimoxazole 40 mg/200 mg per 5 ml Paediatric Suspension (Aspen)** 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 **31 August 2022**.

**Co-Trimoxazole 40 mg/200 mg per 5 ml Paediatric Suspension (Aspen)** is approved for use under Section 19A for the following indications:

*Upper and lower respiratory tract infections; renal and urinary tract infections; genital tract infections; gastrointestinal tract infections; skin and wound infections; septicaemias, and other infections caused by sensitive organisms.*

The s19A approved *UK* product is identical in active ingredient and strength to the Australian registered product. The two products differ in their storage conditions and excipient ingredients. These differences are noted below:

	<b>SEPTRIN 40/200 (trimethoprim/sulfamethoxazole) oral liquid (Aust R 11000)</b>	<b>Co-Trimoxazole 40 mg/200 mg per 5 ml Paediatric Suspension (Aspen)</b>
<b>Storage</b>	Store below 30°C.	Store below 25°C.
<b>Excipients</b>	sorbitol methyl hydroxybenzoate sodium benzoate ethanol <b>Cherry Flavour Artif F1242 (PI 286)</b> <b>sunset yellow</b> <b>allura red</b> <b>citric acid</b> cellulose glycerol polysorbate 80 sodium carmellose saccharin sodium	Sorbitol solution 70% (non-crystallising) (E420 ii) Glycerol (E422) Dispersible Cellulose (E460) Sodium Carmellose Polysorbate 80 (E433) Methyl Hydroxybenzoate (E218) Sodium Benzoate (E211) Saccharin Sodium (E954) Ethanol (96%) <b>Flavour, Banana 81.605P</b> <b>Flavour, Vanilla 407</b> <b>Purified Water to 5 ml</b>

**Co-Trimoxazole 40 mg/200 mg per 5 ml Paediatric Suspension (Aspen)** is 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 bottle label are in English.

Please disregard the foreign product insert and refer to the Australian Product Information for **SEPTRIN sugar-free oral liquid, trimethoprim 40 mg/5 mL and sulfamethoxazole 200 mg/5 mL, 100 mL bottle (AUST R 11000)** (available at <https://www.ebs.tga.gov.au>) when prescribing and administering **Co-Trimoxazole 40 mg/200 mg per 5 ml Paediatric Suspension (Aspen)**.

#### 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 **Co-Trimoxazole 40 mg/200 mg per 5 ml Paediatric Suspension (Aspen)** 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](mailto: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](mailto: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 **SEPTRIN sugar-free oral liquid, trimethoprim 40 mg/5 mL and sulfamethoxazole 200 mg/5 mL, 100 mL bottle (AUST R 11000)**.

Yours sincerely,



Charlotte Griffin

Medicine Access Associate