

MEDICATION SAFETY COMMUNICATION

Information for health professionals in NSW public health organisations

UPDATED: Trimethoprim plus sulfamethoxazole (Septrin®) oral liquid – 8 June 2023	
What's new in this update?	<ul style="list-style-type: none">Resolution date revised.Details of additional S19A alternative included.
Details of affected product(s)	Septrin (trimethoprim 40 mg plus sulfamethoxazole 200 mg per 5 mL) sugar-free oral liquid 100 mL bottle – ARTG 11000
Reason for communication	Disruption to supply
Date issue made apparent	April 2023
Estimated resolution date	Late June 2023 (potential for further extension)

Main indications and use

Trimethoprim plus sulfamethoxazole is an oral antibiotic used for the treatment of 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.

Situation

There is a current disruption to the supply of the Australian registered brand of trimethoprim 40 mg plus sulfamethoxazole 200 mg per 5 mL (Septrin) oral liquid due to manufacturing issues. **Supply may return from late June 2023 however there is a potential for further delays.**

Alternative agents

The following international alternatives have been approved for supply in Australia until 31 August 2023 under Section 19A (S19a) of the Therapeutic Goods Act:

- Co-Trimoxazole paediatric suspension** (trimethoprim 40 mg plus sulfamethoxazole 200 mg per 5 mL) from the United Kingdom which is currently available for purchase from Reach Pharmaceuticals.
- Nopil Fur Kinder Sirup** (trimethoprim 40 mg plus sulfamethoxazole 200 mg per 5 mL) oral syrup 100 mL from Switzerland which is currently available for purchase from Orspec Pharma Pty Ltd.

Further S19A alternatives may become available – see [here](#) for further information.

Precautions, safety issues and other considerations associated with alternative products

The Australian registered product (Septrin) and S19A alternatives are identical in active ingredients and strength, however there are differences in formulation, excipients, storage requirements and presentation. See **Table 1** on the next page for a comparison.

Additional risk mitigation strategies specific to Nopil alternative

As some of the information on the packaging for the S19A alternative Nopil from Switzerland is in German and French, additional labelling will be required to ensure that the instructions for use are clearly articulated in English. The following information should be included on the dispensing label:

- The English spelling of the active ingredients – ‘trimethoprim’ and ‘sulfamethoxazole’
- “Shake before use”
- “Store between 15-25°C in a dry place”
- “Discard unused contents after [DATE]” – date should be 4 weeks after date of opening packaging/dispensing the medicine.

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Table 1. Comparison of Australian registered product and S19A alternative.

	ARTG Product SEPTRIN sugar-free oral liquid	S19A alternative Co-Trimoxazole (United Kingdom)	S19A alternative NOPIL FÜR KINDER SIRUP (Switzerland)
Active ingredients and strength	Trimethoprim 40 mg plus sulfamethoxazole 200 mg per 5 mL	Trimethoprim 40 mg plus sulfamethoxazole 200 mg per 5 mL	Trimethoprim 40 mg plus sulfamethoxazole 200 mg per 5 mL (Note: labelling states 'sulfamethoxazolum' and 'trimethoprimum' – the German spelling for the active ingredients)
Form	Oral liquid	Oral suspension	Oral syrup
Excipients and flavour	<ul style="list-style-type: none"> Flavour – cherry 	<ul style="list-style-type: none"> Flavour – vanilla or banana 	<ul style="list-style-type: none"> Flavour – vanilla 5 mL of syrup contains 1.26 g of usable carbohydrates Contains additional preservatives – sorbic acid and propylparaben
Storage	Store below 25°C. Protect from light.	Store below 25°C. Protect from light.	Store between 15-25 °C in a dry place. Discard within 4 weeks of opening.
Presentation	100 mL bottle. The expiry date is printed on the packaging.	100 mL bottle. The expiry date is printed on the packaging.	100 mL bottle. Some information is written in German and French on the packaging (see Figure 1 below).

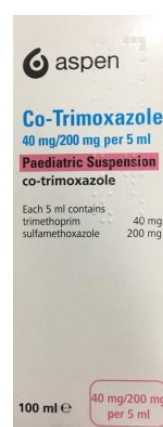


Figure 1. Artwork/packaging of available S19A alternatives Nopil (left) and Co-Trimoxazole (right).

Impacts of this communication on clinical practice

- Actions to address the disruption to the supply of trimethoprim 40 mg plus sulfamethoxazole 200 mg per 5 mL (Septrin) oral liquid should be planned and implemented at a local level by the Drug and Therapeutics Committee in consultation with the relevant clinicians.
- Alternatives are available and can be utilised by facilities after consideration of the above precautions and safety issues in addition to individual patient needs (for example, assessing the suitability of the alternative in patients with diabetes due to the presence of sugar).

Associated regulatory or policy issues

[PD2022_032 Medication Handling](#)

[PD2019_019 Coordination of responses to urgent system-level medicine or medical device issues](#)

Key contacts

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