

30 August 2023

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

Dear Healthcare Professional,

This communication is sent by ORSPEC Pharma to notify your organisation that due to the shortage of **SEPTRIN sugar-free oral liquid, trimethoprim 40 mg/5 mL and sulfamethoxazole 200 mg/5 mL, 100 mL bottle (AUST R 11000)**, ORSPEC Pharma has arranged the supply of an alternative product on a temporary basis.

NOPIL FUR KINDER SIRUP (sulfamethoxazole and trimethoprim 200 mg/40 mg oral syrup 100 mL bottle), is 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 November 2023**.

NOPIL FUR KINDER SIRUP (sulfamethoxazole and trimethoprim 200 mg/40 mg oral syrup 100 mL bottle) 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.

Note to the dispensing pharmacist:

Please provide a copy of the Australian **SEPTRIN sugar-free oral liquid** CMI available at <https://www.ebs.tga.gov.au/> with each dispensing of **NOPIL FUR KINDER SIRUP (sulfamethoxazole and trimethoprim 200 mg/40 mg oral syrup 100 mL bottle)**.

The following information is in German language on the packaging. To ensure patients/carers use and store the product correctly, please include the following information to the dispensing label:

- "Shake before use"
- "Store between 15-25 °C in a dry place"
- "Discard within 4 weeks of opening"

Please note the following differences in excipients between **SEPTRIN sugar-free oral liquid bottle - ARTG 11000** and **NOPIL FUR KINDER SIRUP** to be supplied under section 19A (referred as the S19A products below).

ARTG product excipients (SEPTRIN sugar-free oral liquid bottle - ARTG 11000)(Sulfamethoxazole 200mg/Trimethoprim 40 mg per 5ml oral suspension 100ml bottle)	S19A product excipients (NOFIL FUR KINDER SIRUP (sulfamethoxazole and trimethoprim 200 mg/40 mg per 5ml oral syrup 100 mL bottle))
<ul style="list-style-type: none"> • sorbitol • ethanol • Cherry Flavour Artif F1242 (PI 286) • sunset yellow • allura red • citric acid • cellulose • glycerol • polysorbate 80 • sodium carmellose • saccharin sodium • methyl hydroxybenzoate • sodium benzoate 	<ul style="list-style-type: none"> • Sorbitol 2.1 g • sodium cyclamate • saccharin sodium • Flavouring: Ethyl vanillin, vanillin etc. • Colouring: E150 • Preservative: E216, E218; E200 • 5 ml of syrup contains 1.26g of usable carbohydrates.

NOFIL FUR KINDER SIRUP is registered in the Switzerland and are packaged in the German language. The active ingredient in German language ‘**sulfamethoxazolum/trimethoprimum**’ is equivalent to ‘**sulfamethoxazole/trimethoprim**’ in the English language. The strength ‘sulfamethoxazole 200 mg/5 mL and trimethoprim 40 mg/5 mL’ are clearly distinguishable in the English language. Please disregard the foreign language product insert and refer to the Australian Product Information for **SEPTRIN sugar-free oral liquid bottle (AUST R 11000)** available at <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 with **NOFIL FUR KINDER SIRUP** should be reported by healthcare professionals and patients to ORSPEC Pharma on 024 339 4239 or email at customerservice@orspecpharma.com. Alternatively, this information can be reported to the TGA at <https://www.tga.gov.au/reporting-problems>

Please forward this information to relevant staff members in your organisation. For further information, please contact ORSPEC Pharma on 024 339 4239 or email customerservice@orspecpharma.com.

Yours sincerely,



Deon Scheepers
Managing Director
ORSPEC Pharma