

14th March 2023

Dear Healthcare Professional,

Availability of CECLOR cefaclor 250mg/5mL (as monohydrate) powder for oral liquid bottle, AUST R: 347593 - alternative supply arrangement under Section 19A of the Therapeutic Goods Act.

Due to the shortage of CECLOR cefaclor 250mg/5mL (as monohydrate) powder for oral liquid bottle, AUST R: 347593, Reach Pharmaceuticals has arranged the supply of an alternative product called **DISTACLOR GRANULES FOR SUSPENSION 250 MG/5 ML**, registered and marketed in the UK.

DISTACLOR GRANULES FOR SUSPENSION 250 MG/5 ML 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 **30 November 2023**. for the following indications:

Treatment of the following types of infections caused by or likely to be caused by susceptible organisms: Lower respiratory infections, including pneumonia, bronchitis and exacerbations of chronic bronchitis. Upper respiratory tract infections, including pharyngitis, tonsillitis and otitis media. Skin and skin structure infections. Urinary tract infections including pyelonephritis and cystitis. NOTE: 1. Penicillin is the usual drug of choice in the treatment and prevention of streptococcal infections, including the prophylaxis of rheumatic fever. Ceclor appears to be as effective as phenoxymethyl penicillin in the eradication of streptococci from the nasopharynx; however, substantial data establishing the efficacy of Ceclor in the subsequent prevention of rheumatic fever are not available at present. 2. Appropriate culture and susceptibility studies should be performed to determine susceptibility of the causative organism to cefaclor.

The S19A approved UK product is identical in active ingredient, excipients, and strength to the Australian registered product. **Both products contain sucrose**. A comparison table of differences and additional information is given in the table below:

	ARTG product - CECLOR cefaclor 250mg/5mL (as monohydrate) powder for oral liquid bottle (ARTG: 347593)	S19A product - DISTACLOR cefaclor 250mg in 5mL granules for oral suspension (UK)
Presentation	Pack size: 75 mL	Pack size: 100mL
Reconstitution instructions	Add 45 mL of water in two portions to the dry mixture in the bottle. Shake well after each addition.	Shake the bottle both before and after reconstitution. Add 60mL of water in two portions, shaking after each addition until suspended.
Storage	Dry powder: store below 25°C. Keep the bottle tightly closed.	Store at room temperature 15-25°C. Keep containers tightly closed and protect from light.



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	Reconstituted suspension: store at 2°C to 8°C (Refrigerate. Do not freeze). Use within 14 days and discard remaining portion thereafter.	After reconstitution, the suspension should be stored in a refrigerator (2-8°C) and be used within 14 days.
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Please refer to the Australian Product Information for **CECLOR cefaclor 250mg/5mL (as monohydrate) powder for oral liquid bottle, AUST R: 347593** (available at <https://www.ebs.tga.gov.au>) when prescribing and administering **DISTACLOR GRANULES FOR SUSPENSION 250 MG/5 ML**.

Please note that other Australian registered brands of **cefaclor** suspension may also have different excipients, reconstitution and storage requirements to **DISTACLOR GRANULES FOR SUSPENSION 250 MG/5 ML**. Please refer to the Australian Product Information for the relevant cefalexin suspension product for details on these differences.

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 **DISTACLOR GRANULES FOR SUSPENSION 250 MG/5 ML** 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