20th June 2023

Dear Healthcare Professional,

Availability of ZINNAT cefuroxime (as axetil) 125 mg/5mL granules for oral suspension bottle (AUST R 178687) - alternative supply arrangement under Section 19A of the *Therapeutic Goods Act*.

Due to the discontinuation of the Australian registered ZINNAT CEFUROXIME (AS AXETIL) 125 MG/5ML GRANULES FOR ORAL SUSPENSION BOTTLE (AUST R 178687), Reach Pharmaceuticals has arranged the supply of an alternative product called **ZINNAT cefuroxime (as axetil) 125 mg/5mL granules for oral suspension bottle (UK)** registered and marketed in the United Kingdon.

ZINNAT cefuroxime (as axetil) 125 mg/5mL granules for oral suspension bottle (UK) 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 Date for the following indications:

> *Treatment of the following mild to moderately severe infections caused by sensitive bacteria in paediatric patients aged 3 months to 12 years: tonsillitis and pharyngitis, acute bacterial otitis media.*
> *Penicillin is the usual drug of choice in the treatment and prevention of streptococcal infections, including the prophylaxis of rheumatic fever. Cefuroxime axetil appears to be as effective as phenoxymethylpenicillin in the eradication of streptococci from the nasopharynx; however, substantial data establishing the efficacy of cefuroxime axetil in the subsequent prevention of rheumatic fever are not available at present.*

The S19A approved UK product is identical in active ingredient and strength to the Australian registered product.

Please refer to the Australian Product Information for **ZINNAT CEFUROXIME (AS AXETIL) 125 MG/5ML GRANULES FOR ORAL SUSPENSION BOTTLE (AUST R 178687)** (available at https://www.ebs.tga.gov.au) when prescribing and administering ZINNAT cefuroxime (as axetil) 125 mg/5mL granules for oral suspension bottle (UK).

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 **ZINNAT cefuroxime (as axetil) 125 mg/5mL granules for oral suspension bottle (UK)** 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