17th January 2023

Dear Healthcare Professional,

Availability of IBILEX cefalexin monohydrate 125mg/5mL powder for oral liquid (AUST R 92972) AND IBILEX cefalexin monohydrate 250mg/5mL powder for oral liquid (AUST R 92973) - alternative supply arrangement under Section 19A of the *Therapeutic Goods Act*.

Due to the shortage of the Australian registered IBILEX cefalexin monohydrate 125mg/5mL powder for oral liquid (AUST R 92972) AND IBILEX cefalexin monohydrate 250mg/5mL powder for oral liquid (AUST R 92973), Reach Pharmaceuticals has arranged the supply of an alternative product called **KEFORAL 250 MG/5 ML GRANULES FOR ORAL SUSPENSION,** registered and marketed in Italy. While the name of the active ingredient and strength is identifiable in English, the labelling of this product is in Italian. Please refer to the below table for reconstiutuion, storage, and declarable excipient information.

KEFORAL 250 MG/5 ML GRANULES FOR ORAL SUSPENSION 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 December 2023. for the following indications:

Treatment of the following infections when caused by susceptible strains of the designated microorganisms.

- *Respiratory tract infections. Caused by S. pneumoniae and group A beta-haemolytic streptococci (penicillin is the usual drug of choice in the treatment and prevention of streptococcal infections, including the prophylaxis of rheumatic fever. Cephalexin is generally effective in the eradication of streptococci from the nasopharynx; however, substantial data establishing the efficacy of cephalexin in the subsequent prevention of rheumatic fever are not available at present).*
- *Bacterial sinusitis. Caused by Streptococci, S. pneumoniae and S. aureus (methicillin sensitive only).*
- *Otitis media. Due to S. pneumoniae, staphylococci.*
- *Skin and skin structure infections. Caused by staphylococci and/or streptococci.*
- *Genitourinary tract infections, including acute prostatitis. Caused by E. coli, P. mirabilis, and klebsiella sp.*

The effectiveness of cephalexin in the treatment of bacterial infections of the brain and spinal column has not been established and cephalexin is not indicated in these conditions.

Note: appropriate culture and susceptibility tests should be initiated prior to and during therapy to determine susceptibility of the causative organism to cephalexin. Renal function studies should be performed when indicated.

The S19A approved Italian 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 products **IBILEX cefalexin monohydrate 125mg/5mL powder for oral liquid (AUST R 92972)** **IBILEX cefalexin monohydrate 250mg/5mL powder for oral liquid (AUST R 92973)**	**S19A product** **KEFORAL 250 MG/5 ML GRANULES FOR ORAL SUSPENSION**
Storage and Expiry	Store below 25ºC and protect from light. Upon reconstitution, the suspension must be stored in a refrigerator between 2ºC and 8ºC. Refrigerate. Do not freeze. Discard unused portion 14 days after mixing.	Do not store granules above 25°C. Once prepared, the oral suspensions must be stored in the refrigerator (between 2 and 8°C) and used within 14 days.
Declarable excipients	Contains sucrose.	Contains sucrose.
Reconstitution and preparation	**For both 125mg/5mL and 250mg/5mL** Invert bottle and tap to loosen powder. Add 60mL water in two portions to the dry mixture in the bottle. Shake well placing the bottle horizontal after every addition. Shake the bottle well then accurately measure the correct dose. Always use a metric measure.	**Instructions for preparing the oral suspension** o Shake the bottle well to disperse the powder o Add water up to the level indicated by the arrow on the label o Close the bottle and shake well (by adding water the product turns red) o The volume will drop below the level indicated by the arrow, then add water again, up to the level indicated by the arrow and shake well until a uniform suspension is obtained o Use the syringe or measuring cup for administration o Shake well before each administration.

Please refer to the Australian Product Information for **IBILEX cefalexin monohydrate 125mg/5mL powder for oral liquid (AUST R 92972) AND IBILEX cefalexin monohydrate 250mg/5mL powder for oral liquid (AUST R 92973)** (available at https://www.ebs.tga.gov.au) when prescribing and administering **KEFORAL 250 MG/5 ML GRANULES FOR ORAL SUSPENSION.**

Please note that other Australian registered brands of cefalexin suspension may also have different excipients, reconstitution and storage requirements to **KEFORAL 250 MG/5 ML**

GRANULES FOR ORAL SUSPENSION .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 **KEFORAL 250 MG/5 ML GRANULES FOR ORAL SUSPENSION** 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