ProPharmaceuticalsGroup

Pro Pharmaceuticals Group Pty LTD
ABN: 20 605 457 430
www.propg.com.au

Dear Healthcare Professional,

Shortage of IBILEX 250 cefalexin 250mg/5mL powder for oral liquid bottle

The Australian registered medicine, IBILEX 250 cefalexin 250mg/5mL powder for oral liquid bottle (AUST R: 92973 Active ingredients: cefalexin monohydrate Dosage form: Oral Liquid, powder for Sponsor: Alphapharm Pty Ltd) is currently in shortage due to manufacturing issues.

Pro Pharmaceuticals Group has arranged for the supply of an alternative product, **KEFORAL cefalexin 250mg/5ml granules for oral suspension (Italy)**. This product 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 **31st Dec 2023** for the following indication(s):

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. Cefalexin monohydrate is generally effective in the eradication of streptococci from the nasopharynx; however, substantial data establishing the efficacy of cefalexin monohydrate 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 soft-tissue 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 IBILEX in the treatment of bacterial infections of the brain and spinal column has not been established and IBILEX 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 IBILEX. Renal function studies should be performed when indicated.

KEFORAL cefalexin 250mg/5ml granules for oral suspension (Italy) is registered and marketed in Italy. The labelling and package insert is in Italian. The active ingredient, strength and dosage form are identifiable in English. Pro Pharmaceuticals Group recommends that healthcare professionals refer to the Australian approved Product Information for recommended dosing for various indications.

The s19A approved Italian product is identical in active ingredient and strength to the Australian registered product. A comparison table of differences and additional information is given in the table below:

	ARTG product: IBILEX cefalexin monohydrate 250mg/5mL powder for oral liquid (AUST R 92973)	**S19A product: KEFORAL cefalexin 250mg/5ml granules for oral suspension (Italy)**
Storage and Expiry	Store below 25C and protect from light. Upon reconstitution, the suspension must be stored in a refrigerator between 2C and 8C. Refrigerate. Do not freeze. Discard unused portion 14 days after mixing.	Do not store granules above 25C. Once prepared, the oral suspensions must be stored in the refrigerator (between 2 and 8C) and used within 14 days.
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.

Declarable excipients	Contains sucrose	Contains sucrose

Reporting suspected adverse events is important for the continued monitoring of the safety of all medicines. Any adverse events which are experienced with **KEFORAL cefalexin 250mg/5ml granules for oral suspension (Italy)** must be reported by healthcare professionals, pharmacists, and patients to the TGA at https://www.tga.gov.au/reporting-problems or to Pro Pharmaceuticals Group on 1300077674 or email regulatory@propg.com.au

Any product complaints with **KEFORAL cefalexin 250mg/5ml granules for oral suspension (Italy)** should be reported to Pro Pharmaceuticals Group on 1300 077674 or email regulatory@propg.com.au

For any orders please contact Pro Pharmaceuticals Group on 1300077674 or email orders@propg.com.au

Please forward this information to relevant staff members in your organisation.
For further information, please contact Pro Pharmaceuticals Group on 1300077674 or email info@propg.com.au

Sincerely,
Sandip Manku – Director Pro Pharmaceuticals Group