Pro Pharmaceuticals Group Pty LTD
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Dear Healthcare Professional,

Shortage of CEFALEXIN SANDOZ cefalexin (as monohydrate) 500mg capsule blister pack

Pro Pharmaceuticals Group recognises the importance of supplying essential medicines in Australia and would like to advise you the change in supply status of CEFALEXIN SANDOZ cefalexin (as monohydrate) 500mg capsule blister pack in Australia.

The Australian registered medicine, CEFALEXIN SANDOZ cefalexin (as monohydrate) 500mg capsule blister pack (AUST R: 78980) is currently in shortage due to manufacturing issues.

Pro Pharmaceuticals Group has arranged for the supply of an alternative product, **Cephalexin capsules, USP 500mg (Ascend).** 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 July 2023** for the following indication(s):

Treatment of the following infections when caused by susceptible strains of the designated micro-organisms.

- *Respiratory tract infections.* Caused by *S. pneumoniae* and group A ß-haemolytic Streptococci (penicillin is the usual drug of choice in the treatment and prevention of streptococcal infections, including the prophylaxis of rheumatic fever. Cefalexin is generally effective in the eradication of Streptococci from the nasopharynx; however, substantial data establishing the efficacy of cefalexin 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 cefalexin in the treatment of bacterial infections of the brain and spinal column has not been established and cefalexin 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 cefalexin. Renal function studies should be performed when indicated.

Cephalexin capsules, USP 500mg (Ascend) is registered and marketed in the USA by Ascend Laboratories, LLC, therefore all labelling is 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 US product is identical in active ingredient and strength to the Australian registered product. A comparison table of differences between the products is given below:

	ARTG product **CEFALEXIN SANDOZ cefalexin (as monohydrate) 500mg capsule blister pack (AUST R: 78980)**	*S19A Product* **Cephalexin capsules, USP 500mg (Ascend)**
Excipients	Magnesium stearate, and microcrystalline cellulose. The capsule shell also contains gelatin and titanium dioxide.	Anhydrous lactose, colloidal silicon dioxide, magnesium stearate, FD & C Blue No. 1 and D & C Yellow No. 10, gelatin, sodium lauryl sulphate, titanium dioxide. The imprinting ink contains: *shellac, propylene glycol, strong ammonia solution and potassium hydroxide. Also black iron oxide.*
Additional warnings		This medicine contains **lactose**, this excipient **is not** declared on the product label.
Pack size	Each blister pack contains 20 capsules.	Bottles of 100 Bottles of 500
Presentation	The capsules are white opaque in colour, containing a white to yellowish powder.	A white to off white powder filled into size 0 capsules (light green cap and light green body) that are imprinted with "219" on the both cap and body in edible black ink.
Storage	Store below 25C.	Store at 20C to 25C excursions permitted to 15 to 30C.

Reporting suspected adverse events is important for the continued monitoring of the safety of all medicines. Any adverse events which are experienced with Cephalexin capsules, USP 500mg (Ascend) 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 **Cephalexin capsules, USP 500mg (Ascend)** 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