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

Dear Healthcare Professional,

Shortage of CURAM DUO 400/57 amoxicillin/clavulanic acid powder for suspension bottle (AUST R 147109).

Pro Pharmaceuticals Group recognises the importance of supplying essential medicines in Australia and would like to advise you of the change in supply status of CURAM DUO 400/57 amoxicillin/clavulanic acid powder for suspension bottle (AUST R 147109) in Australia.

The Australian registered medicine, CURAM DUO 400/57 amoxicillin/clavulanic acid powder for suspension bottle (AUST R 147109) Sponsor: Sandoz Pty Ltd is currently in shortage due to manufacturing issues.

Pro Pharmaceuticals Group has arranged for the supply of an alternative product, **Amoxicillin and clavulanate potassium for oral suspension, USP 400mg/57mg per 5mL (Aurobindo).** 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 January 2024** for the following indication(s):

Amoxicillin and clavulanic acid is indicated for the short-term treatment of the following bacterial infections when caused by sensitive organisms:
• skin and skin structure infections;
• urinary tract infections (complicated and uncomplicated);
• upper respiratory tract infections including sinusitis and otitis media;
• lower respiratory tract infections including acute exacerbations of chronic bronchitis and community acquired pneumonia.
Appropriate culture and susceptibility studies should be performed to identify the causative organism(s) and determine its (their) susceptibility to amoxicillin/clavulanic acid). However, when there is reason to believe an infection may involve any of the beta-lactamase producing organisms listed in Microbiology, therapy may be instituted prior to obtaining the results from bacteriological and susceptibility studies. Once these results are known, therapy should be adjusted if appropriate.
The treatment of mixed infections caused by amoxicillin susceptible organisms and betalactamase producing organisms susceptible to amoxicillin and clavulanic acid should not require the addition of another antibiotic due to the amoxicillin content of the product.

Amoxicillin and clavulanate potassium for oral suspension, USP 400mg/57mg per 5mL (Aurobindo) is registered and marketed in the USA by Aurobindo Pharma Limited, therefore all labelling is in English.

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 **CURAM DUO 400/57** amoxicillin 400 mg/5mL (as trihydrate) / clavulanic acid 57 mg/5mL (as potassium clavulanate) powder for suspension bottle (AUST R 147109)	*S19A Product* **Amoxicillin and Clavulanate Potassium for Oral Suspension, USP, 400mg/57mg per 5mL (Aurobindo)**
Excipients	lemon flavouring 15.12.0598 peach-apricot flavour 26F22 citric acid, sodium citrate, aspartame, purified talc, orange 55301 AP0551 guar gum and silicon dioxide. Contains sulfites.	aspartame orange flavour, xanthan gum silicon dioxide, succinic acid, hypromellose,
Additional warnings		This medicine contains **aspartame**, this excipient **is not** declared on the product label.
Pack size	Bottles of 60mL	**Bottles of 50mL and 100mL** **Please note the differences in the bottle size and ensure the patient/carer is aware of the prescribed treatment duration.**
Storage	Store dry powder below 25°C. Under these conditions, the shelf life is 3 years. Store reconstituted suspension at 2°C to 8°C in a refrigerator. Under these conditions, the shelf life is 7 days.	Store at 20° to 25°C (68° to 77°F). Store reconstituted suspension under refrigeration. Discard unused suspension after 10 days. Keep out of the reach of children.

Pro Pharmaceuticals Group recommends that healthcare professionals refer to the Australian approved Product Information for recommended dosing, available at: https://www.ebs.tga.gov.au.

Reporting suspected adverse events is important for the continued monitoring of the safety of all medicines. Any adverse events which are experienced with Amoxicillin and clavulanate potassium for oral suspension, USP 400mg/57mg per 5mL (Aurobindo) 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 **Amoxicillin and clavulanate potassium for oral suspension, USP 400mg/57mg per 5mL (Aurobindo)** 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