



ProPharmaceuticalsGroup

Pro Pharmaceuticals Group Pty LTD

ABN: 20 605 457 430

www.propg.com.au

31/8/22

Dear Healthcare Professional,

Shortage of AUGMENTIN DUO FORTE tablet blister pack 875mg/125mg (Amoxicillin Trihydrate and Potassium Clavulanate)

Pro Pharmaceuticals Group recognises the importance of supplying essential medicines in Australia and would like to advise you the change in supply status of AUGMENTIN DUO FORTE tablet blister pack 875mg/125mg (Amoxicillin Trihydrate and Potassium Clavulanate) in Australia.

The Australian registered medicine, AUGMENTIN DUO FORTE tablet blister pack 875mg/125mg (Amoxicillin Trihydrate and Potassium Clavulanate) AUST R: 54900 sponsored by Aspen Pharmacare Australia is currently in shortage due to an unexpected increase in consumer demand.

Pro Pharmaceuticals Group has arranged for the supply of an alternative product, **AMOXICILLIN AND CLAVULANATE POTASSIUM tablets 875mg/125mg (Micro Labs)** . 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 2023 for the following indication(s):

AMOXICILLIN AND CLAVULANATE POTASSIUM tablets are indicated for short term treatment of bacterial infections at the following sites when caused by sensitive organisms. * Urinary Tract Infections (uncomplicated and complicated) * Lower Respiratory Tract Infections, including community acquired pneumonia and acute exacerbations of chronic bronchitis * Upper Respiratory Tract Infections, such as sinusitis, otitis media and recurrent tonsillitis * Skin and Skin Structure Infection. Appropriate culture and susceptibility studies should be performed to identify the causative organism(s) and determine its (their) susceptibility to AMOXICILLIN AND CLAVULANATE POTASSIUM tablets, however, when there is reason to believe an infection may involve any of the β -lactamase producing organisms listed above, 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 β lactamase producing organisms susceptible to AMOXICILLIN AND CLAVULANATE POTASSIUM tablets should not require the addition of another antibiotic due to the amoxicillin content of these products.

AMOXICILLIN AND CLAVULANATE POTASSIUM tablets 875mg/125mg (Micro Labs) is registered and marketed in the USA by Micro Labs USA, Inc.

A comparison table of differences between Australian registered product and the USA product is given below:

	ARTG product	S19A Product
	AUGMENTIN DUO FORTE tablet blister pack 875mg/125mg (Amoxicillin Trihydrate and Potassium Clavulanate) AUST R: 54900	Amoxicillin and Clavulanate Potassium 875 mg/125 mg Tablets, USP (Micro Labs)
Pack size	Blister packs of 10 tablets	Bottles of 20
Storage	Store below 25 degrees Celsius.	Store at 20° to 25°C (68° to 77°F)

Excipients	microcrystalline cellulose, magnesium stearate, sodium starch glycolate colloidal anhydrous silica The tablet coating contains: titanium dioxide, hypromellose 5cps & 15cps, Macrogol 4000, Macrogol 6000	silicon dioxide, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, sodium starch glycolate titanium dioxide ethylcellulose talc
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Pro Pharmaceuticals Group recommends that healthcare professionals refer to the Australian approved Product Information for recommended dosing for various indications. This information can be found here: <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 tablets 875mg/125mg (Micro Labs) 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 tablets 875mg/125mg (Micro Labs)** 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