

Turboclav®

Cefuroxime and Clavulanic Acid
Tablet

Description

Turboclav® (Cefuroxime and Clavulanic Acid) is a well-characterized and effective antibacterial agent, which has broad-spectrum bactericidal activity against a wide range of common pathogens, including β -lactamase producing strains. Cefuroxime has good stability to bacterial β -lactamase and consequently is active against many ampicillin-resistant and amoxicillin-resistant strains.

Indications

Turboclav® (Cefuroxime and Clavulanic Acid) is indicated in the treatment of:

1. *Upper respiratory tract infections*: for example nose and throat infections such as otitis media, sinusitis, tonsillitis and pharyngitis.
2. *Lower respiratory tract infections*: for example acute bronchitis, acute exacerbations of chronic bronchitis and pneumonia.
3. *Skin and soft tissue infections*: such as furunculosis, pyoderma and impetigo.
4. *Genito-urinary tract infections*: such as pyelonephritis, urethritis and cystitis.
5. *Gonorrhoea*: acute uncomplicated gonococcal urethritis, and cervicitis.
6. Early Lyme disease & subsequent prevention of late Lyme disease.

Dosage and Administration

Adolescents & Adults:

Pharyngitis or Tonsillitis- 250 mg twice daily for 5-10 days.

Acute bacterial maxillary sinusitis- 250 mg twice daily for 10 days.

Acute bacterial exacerbation of chronic bronchitis- 250-500 mg twice daily for 10 days.

Secondary bacterial infections of acute bronchitis- 250-500 mg twice daily for 5-10 days.

Community acquired pneumonia- 250-500 mg twice daily for 5-10 days.

Uncomplicated skin & skin-structure infections- 250-500 mg twice daily for 10 days
MDR Typhoid fever- 500 mg twice daily for 10-14 days.

Uncomplicated urinary tract infection- 250 mg twice daily for 7-10 days.

Uncomplicated gonorrhoea- 1000 mg single dose.

Lyme disease- 500 mg twice daily for 20 days

Pediatric patients (3 months to 12 years):

Pharyngitis or Tonsillitis- 20 mg/kg/day in two divided doses for 5-10 days.

Acute otitis media- 30 mg/kg/day in two divided doses for 10 days.

Acute bacterial maxillary sinusitis- 30 mg/kg/day in two divided doses for 10 days.

Community acquired pneumonia- 30 mg/kg/day in two divided doses for 5-10 days

MDR Typhoid fever- 30 mg/kg/day in two divided doses for 10-14 days.

Uncomplicated skin & skin-structure infection- 30 mg/kg/day in two divided doses for 10 days.

Uncomplicated urinary tract infection- 20 mg/kg/day in two divided doses for 7-10 days.

Turboclav® may be administered without regard to meals.

Contraindications

Turboclav® is contraindicated in patients with known hypersensitivity to Cephalosporins and Pseudomembranous colitis. It is also contraindicated in *Clostridium difficile* bacterial infection, history of cholestatic jaundice or hepatic dysfunction associated with Amoxicillin and Clavulanate, seizures associated with use of this drug.

Side Effects

Generally Cefuroxime and Clavulanic acid are well tolerated. However, a few side effects like nausea, vomiting, diarrhea, abdominal

discomfort or pain may occur.

Acute Overdosage

Excessively large doses of all Cephalosporins can cause cerebral irritation and may cause convulsions. This complication is unlikely to occur in routine practice unless the patient is in renal failure. Hemodialysis or peritoneal dialysis can remove Turboclav®.

Precaution

As with other antibiotics, prolonged use of Turboclav® may result in the over growth of nonsusceptible organisms (e.g. *Candida*, *Enterococci*, *Clostridium difficile*) which may require interruption of treatment.

Use in Pregnancy & Lactation

While all antibiotics should be avoided in the first trimester if possible, Turboclav® has been safely used in later pregnancy to treat urinary and other infections. Turboclav® is excreted in human milk, and consequently caution should be exercised when Turboclav® is administered to a nursing mother.

Drug Interaction

Probenecid: Concomitant administration of probenecid with cefuroxime increases the area under the serum concentration versus time curve by 50%.

Antacids: Drugs that reduce gastric acidity may result in a lower bioavailability of Turboclav® compared with that of fasting state and tend to cancel the effect of postprandial absorption.

Oral contraceptives: In common with other antibiotics, cefuroxime may affect the gut flora, leading to lower estrogen reabsorption and reduced efficacy of combined oral estrogen/progesterone.

Pharmaceutical Precautions

Keep out of the reach of children. Keep in a cool and dry place. Protect from light.

Commercial Pack

Turboclav® 250 Tablet: Box containing 12 tablets in 3 x 4's Alu-Alu form packs. Each film coated tablet contains Cefuroxime Axetil USP equivalent to Cefuroxime 250 mg and Clavulanate Potassium USP equivalent to Clavulanic Acid 62.5 mg.

Turboclav® 500 Tablet: Box containing 8 tablets in 2 x 4's Alu-Alu form packs. Each film coated tablet contains Cefuroxime Axetil USP equivalent to Cefuroxime 500 mg and Clavulanate Potassium USP equivalent to Clavulanic Acid 125 mg.



Manufactured by

BEXIMCO PHARMACEUTICALS LTD.

TONGI, BANGLADESH

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