Clacido®

Amoxicillin + Clavulanic Acid

Presentation

Clacido® Tablet 375 mg: Each film coated tablet contains Amoxicillin Trihydrate BP 286.95 mg equivalent to Amoxicillin 250 mg and Clavulanate Potassium USP 148.840 mg equivalent to Clavulanic Acid 125 mg.

Clacido® Tablet 625 mg: Each film coated tablet contains Amoxicillin Trihydrate BP 573.900 mg equivalent to Amoxicillin 500 mg and Clavulanate Potassium USP 148.840 mg equivalent to Clavulanic Acid 125 mg.

Clacido® Tablet 1 g: Each film coated tablet contains Amoxicillin Trihydrate BP 1004.325 mg equivalent to Amoxicillin 875 mg and Clavulanate Potassium USP 148.840 mg equivalent to Clavulanic Acid 125 mg.

Clacido® Powder for Suspension: Each 5 ml reconstituted suspension contains Amoxicillin Trihydrate BP 143.475 mg equivalent to Amoxicillin 125 mg and Clavulanate Potassium USP 37.21 mg equivalent to Clavulanic Acid 31.25 mg.

Clacido® bid Powder for Suspension: Each 5 ml reconstituted suspension contains Amoxicillin Trihydrate BP 459.120 mg equivalent to Amoxicillin 400 mg and Clavulanate Potassium USP 68.466 mg equivalent to Clavulanic Acid 57.50 mg.

Clacido® I.V. Injection 1.2 g: Each vial contains sterile Amoxicillin Sodium BP 1060.20 mg equivalent to Amoxicillin 1000 mg and Clavulanate Potassium USP 238.14 mg equivalent to Clavulanic Acid 200 mg.

Description

Clacido® is an antibacterial combination consisting of the antibiotic Amoxicillin and the Beta-lactamase inhibitor Clavulanic acid. Amoxicillin has a broad spectrum of bactericidal activity against many gram-positive & gram-negative microorganisms but it is susceptible to degradation by beta-lactamases and therefore the spectrum of activity does not include microorganisms, which produce these enzymes. Clavulanic acid possesses the ability to inactivate a wide range of beta-lactamase enzymes commonly found in microorganisms resistant to penicillins and cephalosporins. Thus Clavulanic acid in Clacido® protects Amoxicillin from degradation by beta-lactamase enzymes and effectively extends the antibiotic spectrum to embrace a wide range of microorganisms.

Indications

Clacido® is indicated for short-term treatment of bacterial infections at the following sites:

- Upper respiratory tract infections (including ENT) e.g. recurrent tonsillitis, sinusitis, otitis media.
- Lower respiratory tract infections e.g. acute exacerbation of chronic bronchitis, lobar and bronchopneumonia.
- Genito-urinary tract infections e.g. cystitis, urethritis, pyelonephritis.
- Skin and soft tissue infections.
- Bone and joint infections e.g. osteomyelitis.
- Other infections e.g. intra-abdominal sepsis, septic abortion, puerperal sepsis, septicaemia, peritonitis, post-surgical infections.

Dosage & Administration

Tablet

Adults

The usual adult dose is one Clacido® 625 mg tablet every 12 hours or one Clacido® 375 mg tablet every 8 hours. For more severe infections and infections of the respiratory tract, the dose should be one Clacido® 1 gm tablet every 12 hours or one Clacido® 625 mg tablet every 8 hours.

Suspension

Pediatric Patients

Neonates and Infants Aged <12 weeks (<3 months):

The recommended dose of Clacido® is 30 mg/kg/day divided every 12 hours

Patients Aged 12 weeks (3 months) and Older:

	Dosing regimen	
	Every 12 hours	Every 8 hours
	400 mg/5 mL oral suspension	125 mg/5 ml oral suspension
Otitis media, Sinusitis, Lower respiratory tract infections and more severe infections	45 mg/kg/day every 12 hours	40 mg/kg/day every 8 hours
Less severe infections	25 mg/kg/day every 12 hours	20 mg/kg/day every 8 hours

Patients Weighing 40 kg or more: Pediatric patients weighing 40 kg or more should be dosed according to adult recommendations.

The normal duration of treatment was 7 to 10 days.

Clacido® may be taken without regard to meals; however, absorption of Clavulanate potassium is enhanced when Amoxicillin/Clavulanic acid is administered at the start of a meal. To minimize the potential for gastrointestinal intolerance, Amoxicillin/Clavulanic acid should be taken at the start of the meal.

I.V. Injection

Adults and children over 12 years:

Usually 1.2 g eight hourly. In more serious infections, increase frequency to six-hourly intervals.

Children 3 months-12 years:

Usually 30 mg/kg eight hourly. In more serious infections, increase frequency to six-hourly intervals.

Children 0-3 months:

30 mg/kg eight hourly (every 12 hours in the perinatal period and in premature infants).

Adult dosage for surgical prophylaxis:

The usual dose is 1.2 g at the induction of anaesthesia , for high risk of infection, (e.g. colorectal surgery) may require three and up to four doses of 1.2 g intravenous in a 24-hour period.

Dosage in renal impairment

Adults

Mild impairment (creatinine clearance >30 ml/min)	Moderate impairment (creatinine clearance 10-30 ml/min)	Severe impairment (creatinine clearance <10 ml/min)
No change in dosage	One Clacido® 375 mg tablet or one Clacido® 625 mg tablet every 12 hours or 1.2 g IV followed by 600 mg IV 12 hourly.	One Clacido® 375 mg tablet or one Clacido® 625 mg tablet every 24 hours or 1.2 g IV followed by 600 mg IV 24 hourly. Dialysis decreases serum concentrations of Clacido® and an additional 600 mg IV dose may need to be given during dialysis and at the end of dialysis.

Children

Similar reductions in dosage should be made for children.

Dosage in hepatic impairment

Dose with caution; monitor hepatic function at regular intervals.

Warnings and Precautions

Clacido® should be used with care in patients on anti-coagulation therapy or with severe hepatic dysfunction. In patients with moderate or severe renal impairment, dosage should be adjusted. During the administration of high dose of Clacido® adequate fluid intake and urinary output should be maintained to minimize the possibility of crystalluria.

Contraindications

- History of a serious hypersensitivity reaction to Clacido® or to other beta-lactams (e.g., penicillins or cephalosporins).
- History of cholestatic jaundice/hepatic dysfunction associated with Clacido®.

Adverse Reactions

The most frequently reported adverse effects:

Diarrhea/loose stools (9%), Nausea (3%), Skin rashes and Urticaria (3%), Vomiting (1%) and Vaginitis (1%)

Drug Interactions

- Co-administration with probenecid is not recommended
- Concomitant use of Clacido® and oral anticoagulants may increase the prolongation of prothrombin time.
- Coadministration with allopurinol increases the risk of rash
- Clacido® may reduce efficacy of oral contraceptives

Pregnancy & Lactation

Pregnancy Category B. This drug should be used during pregnancy only if clearly needed. Amoxicillin has been shown to be excreted in human milk. Caution should be exercised when amoxicillin/clavulanate potassium is administered to a nursing woman.

Overdose

Gastrointestinal symptoms and disturbance of the fluid and electrolyte balances may be evident. Amoxicillin/Clavulanate potassium can be removed from the circulation by haemodialysis.

Storage

Clacido® Tablet: Should be stored at a temperature not exceeding 25 ^{0}C in a dry place. Protect from light and moisture.

Clacido® Suspension: Should be stored at a temperature not exceeding 25 ^{0}C in a dry place. Protect from light and moisture. Once reconstituted suspension should be kept in a cool place preferably in refrigerator 2-8 ^{0}C (but not frozen) and should be used by 7 days.

Clacido® Injection: Should be stored at a temperature not exceeding 25 ^{0}C in a dry place. Protect from light and moisture. Use within 20 minutes of reconstitution.

Packs

Clacido® Tablet 375 mg: Each box contains 3 x 6's film coated tablets in Alu-Alu blister pack.

Clacido® Tablet 625 mg: Each box contains 3 x 6's film coated tablets in Alu-Alu blister pack.

Clacido® Tablet 1 g: Each box contains 2 x 6's film coated tablets in Alu-Alu blister pack.

Clacido® Powder for Suspension: Bottle containing dry powder to make 100 ml suspension.

Clacido® bid Powder for Suspension: Bottle containing dry powder to make 35 ml suspension.

Clacido® I.V. Injection 1.2g: Each vial contains Amoxicillin Sodium BP 1060.20 mg equivalent to Amoxicillin 1000 mg and Clavulanate Potassium USP 238.14 mg equivalent to Clavulanic Acid 200 mg, one ampoule containing 20 ml of sterile water for injection. It also contains a complementary pouch comprising sterile disposable syringe (20 ml), butterfly needle, alcohol pad, first aid bandage and ampoule breaker.

Medicine: Keep out of reach of children

Healthcare

Manufactured by

Sanofi Bangladesh Limited, Tongi, Gazipur

for Healthcare Pharmaceuticals Ltd.

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