Avloclav

Amoxicillin and Clavulanic Acid

Description

Avloclav 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 and 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 combination of Amoxicillin protects Amoxicillin from degradation by beta-lactamase enzymes and effectively extends the antibiotic spectrum to embrace a wide range of microorganisms.

Indications

Avloclav is indicated for short term treatment of bacterial infections at the following sites:

- Upper respiratory tract infections including tonsillitis, sinusitis, otitis media
- Lower respiratory tract infections including acute and chronic bronchitis, lobar and bronchopneumonia
- Genitourinary tract infections including cystitis, urethritis, pyelonephritis
- Skin and soft tissue infections
- Bone and joint infections including osteomyelitis
- Other infections including septic abortion, puerperal sepsis, intra-abdominal sepsis

Dosage and administration

Dose of Avloclav tablets

Adults and children over 12 years

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

Dose of Avloclav powder for suspensions

Neonate: 0.25 ml/kg three times daily.
1 month to 1 year: 0.25 ml/kg three times daily, dose doubled in severe infection.
1 to 6 years: 5 ml three times daily or 0.25 ml/kg three times daily, dose doubled in severe infection.
6 to 12 years: 10 ml three times daily, dose doubled in severe infection.

Avloclav bid powder for suspension:

2 months to 2 years: 0.15 ml/kg twice daily, dose doubled in severe infection.
2 to 6 years (13 to 21 kg): 2.5 ml twice daily, dose doubled in severe infection.
7 to 12 years (22 to 40 kg): 5 ml twice daily, dose doubled in severe infection.
12 to 18 years (over 40 kg): 10 ml twice daily, three times daily in severe infection.

Direction for reconstitution

For preparation of 100 ml **Avloclav** *suspension*

Shake the bottle to loosen powder before mixing the water. Add 85 ml of boiled and cooled water to the dry powder. For ease of preparation, add water to the bottle in two portions. Shake well after each addition until all the powder is in suspension.

For preparation of 50 ml **Avloclav** *bid suspension*

Shake the bottle to loosen powder before mixing the water. Add 43 ml of boiled and cooled water to the dry powder. For ease of preparation, add water to the bottle in two portions. Shake well after each addition until all the powder is in suspension.

Dose of Avloclav injections

Adults

Usually 1.2 g every 8 hours, increased in more severe infections to 1.2 g every 6 hours.

Adult dosage for surgical prophylaxis

The usual dose is 1.2 g at induction, for high risk procedures (e.g., colorectal surgery) up to 2 to 3 further doses of 1.2 g may be given every 8 hours.

Children

0 to 3 months: 30 mg/kg every 8 hours (every 12 hours in the perinatal period and in premature infants).

3 months to 12 years: Usually 30 mg/kg every 8 hours increased in more serious infections to 30 mg/kg every 6 hours.

Dosing in renal impairment

Amoxicillin is primarily eliminated by the kidney and dosage adjustment is usually required in patients with severe renal impairment (GFR <30 mL/min).

Reconstitution for IV injection

Avloclav 0.6 IV injection can be reconstituted by dissolving the powder in 10 ml water for injection BP.

Avloclav 1.2 IV injection can be reconstituted by dissolving the powder in 20 ml water for injection BP.

Pregnancy and lactation

Pregnancy

There are no adequate and well controlled studies in pregnant women. This drug should be used during pregnancy only if clearly needed.

Lactation

Amoxicillin has been shown to be excreted in human milk. However, caution should be exercised when amoxicillin plus clavulanic acid is administered to a lactating woman.

Side effects
The most common side effects of the combination of amoxicillin plus clavulanic acid are diarrhoea, pseudomembranous colitis, indigestion, nausea, vomiting, candidiasis, urticarial and erythematous rashes. Rarely erythema multiforme, Stevens-Johnson Syndrome and exfoliative dermatitis have been reported.

Contraindications
The combination of amoxicillin plus clavulanic acid is contraindicated in patient with known hypersensitivity to penicillin. It is contraindicated in patients with known hypersensitivity to any of the component of this product. Attention should be paid to possible cross sensitivity with other beta-lactam antibiotics e.g., cephalosporins. It is also contraindicated for patients with previous history of penicillin associated cholestatic jaundice.

Warnings and precautions
This combination 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 this combination adequate fluid intake and urinary output should be maintained to minimize the possibility of crystalluria.

Drug interactions
Prolongation of bleeding time and prothrombin time has been reported in some patients receiving the combination of amoxicillin plus clavulanic acid. In common with other broad-spectrum antibiotics, this combination may reduce the efficacy of oral contraceptives and patient should be warned accordingly. Concomitant use of allopurinol during treatment with amoxicillin can increase the likelihood of allergic skin reactions. There are no data on the concomitant use of the combination of amoxicillin plus clavulanic acid with allopurinol.

Overdose
Problems of overdose with the combination of amoxicillin plus clavulanic acid are unlikely to occur, if encountered gastrointestinal symptoms and disturbance of the fluid and electrolyte balances may be evident. The combination of amoxicillin plus clavulanic acid may be removed from the circulation by haemodialysis.

Pharmaceutical precautions
- Store in a cool (below 25°C) and dry place protected from light.
- Keep away from the reach of children.
- After reconstitution, the suspension must be kept in 2°C-8°C temperature in a refrigerator and consumed within 7 days.
- For injection, use within 20 minutes of reconstitution and should not use intramuscularly.
- To be applied only on the prescription of a registered physician.

Presentation
Avloclav 375 tablet**:** Each coated tablet contains Amoxicillin Trihydrate BP equivalent to Amoxicillin 250 mg and diluted Potassium Clavulanate BP equivalent to Clavulanic Acid 125 mg.

Avloclav 625 tablet**:** Each coated tablet contains Amoxicillin Trihydrate BP equivalent to Amoxicillin 500 mg and diluted Potassium Clavulanate BP equivalent to Clavulanic Acid 125 mg.

Avloclav 1 g tablet**:** Each coated tablet contains Amoxicillin Trihydrate BP equivalent to Amoxicillin 875 mg and diluted Potassium Clavulanate BP equivalent to Clavulanic Acid 125 mg.

Avloclav powder for suspension**:** After reconstitution, each 5 ml contains Amoxicillin Trihydrate BP equivalent to Amoxicillin 125 mg and diluted Potassium Clavulanate BP equivalent to Clavulanic Acid 31.25 mg.

Avloclav bid powder for suspension**:** After reconstitution, each 5 ml contains Amoxicillin Trihydrate BP equivalent to Amoxicillin 400 mg and diluted Potassium Clavulanate BP equivalent to Clavulanic Acid 57.5 mg.

Avloclav 0.6 IV injection**:** Each vial contains sterile mixture of Amoxicillin Sodium BP equivalent to Amoxicillin 500 mg and Potassium Clavulanate BP equivalent to Clavulanic Acid 100 mg.

Avloclav 1.2 IV injection**:** Each vial contains sterile mixture of Amoxicillin Sodium BP equivalent to Amoxicillin 1000 mg and Potassium Clavulanate BP equivalent to Clavulanic Acid 200 mg.

Package quantities

Avloclav 375 tablet: Each box contains 18 tablets in 3x6's Alu-Alu blister pack.
Avloclav 625 tablet**:** Each box contains 18 tablets in 3x6's Alu-Alu blister pack.
Avloclav 1 g tablet: Each box contains 12 tablets in 2x6's Alu-Alu blister pack.
Avloclav powder for suspension: Dry powder in a glass bottle for preparation of 100 ml suspension.
Avloclav bid powder for suspension: Dry powder in a glass bottle for preparation of 50 ml of suspension.
Avloclav 0.6 IV injection: Each combipack contains 1 vial of sterile mixture of Amoxicillin Sodium BP equivalent to Amoxicillin 500 mg and Potassium Clavulanate BP equivalent to Clavulanic Acid 100 mg, 1 ampoule of 10 ml water for injection BP and 1 disposable syringe (10 ml).

Avloclav 1.2 IV injection: Each combipack contains 1 vial of sterile mixture of Amoxicillin Sodium BP equivalent to Amoxicillin 1000 mg and Potassium Clavulanate BP equivalent to Clavulanic Acid 200 mg, 1 ampoule of 20 ml water for injection BP and 1 disposable syringe (20 ml).

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ACI Limited
Godnyl, Narayanganj, Bangladesh