

Tyclav[®]

Amoxicillin and Clavulanic Acid
Tablet, Powder for Suspension and Injections

Description

Tyclav[®] is an antibacterial combination consisting of the antibiotic Amoxicillin and the b-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 b-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 b-lactamase enzymes commonly found in microorganisms resistant to penicillins and cephalosporins. Thus Clavulanic acid in combination of Amoxicillin and Clavulanic acid protects Amoxicillin from degradation by b-lactamase enzymes and effectively extends the antibiotic spectrum to embrace a wide range of microorganisms.

Indication and Usage

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

1. Upper respiratory tract infections (including ENT); e.g., tonsillitis, sinusitis, otitis media.
2. Lower respiratory tract infections; e.g., acute and chronic bronchitis, lobar and bronchopneumonia.
3. Genito-urinary tract infections; e.g., cystitis, urethritis, pyelonephritis.
4. Skin and soft tissue infections.
5. Bone and joint infections; e.g., osteomyelitis.
6. Other infections; e.g., septic abortion, puerperal sepsis, intra-abdominal sepsis, etc.

Dosage and Administrations

Dose of Tablets

Adults and children over 12 years:

The usual adult dose is one Tyclav[®] 625 Tablet every 12 hours or one Tyclav[®] 375 Tablet every 8 hours. For more severe infections and infections of the respiratory tract, the dose should be one Tyclav[®] 1 g Tablet every 12 hours or one Tyclav[®] 625 Tablet every 8 hours.

Dose of Powder for Suspensions

Tyclav[®] Powder for Suspension:

Neonate: 0.25 ml/kg 3 times daily.

1 month–1 year: 0.25 ml/kg 3 times daily, dose doubled in severe infection.

1–6 years: 5 ml 3 times daily or 0.25 ml/kg 3 times daily, dose doubled in severe infection.

6–12 years: 10 ml 3 times daily, dose doubled in severe infection.

Tyclav[®] bid Powder for Suspension:

2 month–2 years: 0.15 ml/kg twice daily, doubled in severe infection.

2–6 years (13–21 kg): 2.5 ml twice daily, doubled in severe infection.

7–12 years (22–40 kg): 5 ml twice daily, doubled in severe infection.

12-18 years (over 40 kg): 10 ml twice daily, three times daily in severe infection.

Dose of 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 2-3 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.

Precautions

Tyclav[®] 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 Tyclav[®] adequate fluid intake and urinary output should be maintained to minimize the possibility of crystalluria.

Contraindications

History of Penicillin hypersensitivity. Attention should be paid to possible cross sensitivity with other beta-lactam antibiotics e.g., cephalosporins. Also contraindicated for patients with previous history of Tyclav[®] or penicillin associated cholestatic jaundice.

Side Effects

Side effects, as with Amoxicillin, are uncommon and mainly of a mild and transitory nature. Diarrhoea, pseudomembranous colitis, indigestion, nausea, vomiting and candidiasis have been reported. If gastrointestinal side effects occur with oral therapy, that may be reduced by taking Tyclav[®] at the start of meals. Hepatitis and cholestatic jaundice have been reported rarely but are usually reversible. Urticarial and erythematous rashes sometimes occur. Rarely erythema multiforme, Stevens-Johnson Syndrome and exfoliative dermatitis have been reported. In common with other beta-lactam antibiotics angioedema and anaphylaxis have been reported.

Use in Pregnancy and Lactation

Amoxicillin and Clavulanic acid has been used orally in human pregnancy in a limited number of cases with no untoward effect; however use of Tyclav[®] in pregnancy is not recommended unless considered essential by the physician. During lactation, trace quantities of Amoxicillin can be detected in breast milk.

Drug Interaction

Prolongation of bleeding time and prothrombin time has been reported in some patients receiving Tyclav[®]. In common with other broad-spectrum antibiotics, Tyclav[®] 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 Tyclav[®] with allopurinol.

Direction for Reconstitution:

For preparation of 100 ml Suspension:

Shake the bottle to loosen powder. Add 95 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 bid Suspension:

Shake the bottle to loosen powder. 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.

Reconstitution Information for Injection:

Tyclav[®] 1.2 IV injection can be reconstituted by dissolving the powder in 20 ml Water for Injection BP.

Tyclav[®] 0.6 IV injection can be reconstituted by dissolving the powder in 10 ml Water for Injection BP.

Overdosage:

Problems of overdose with Tyclav[®] are unlikely to occur, if encountered gastrointestinal symptoms and disturbance of the fluid and electrolyte balances may be evident. Tyclav[®] may be removed from the circulation by haemodialysis.

Pharmaceutical Precautions

For tablet

Keep in a cool and dry place, below 25o C. Protect from light.

For suspension

Keep the bottle tightly closed. The reconstituted suspension should be stored in a cool place preferably in a refrigerator and use within 7 days of reconstitution.

For injection

Use within 20 minutes of reconstitution, do not freeze. Not for intramuscular use. Keep in a cool and dry place. Protect from light.

Commercial Packs:

Tyclav[®] 375 Tablet: Each box contains 18 tablets in 3X6's Alu-Alu form packs. Each film coated tablet contains Amoxicillin Trihydrate BP equivalent to 250 mg Amoxicillin and Clavulanate Potassium USP equivalent to Clavulanic Acid 125 mg.

Tyclav[®] 625 Tablet: Each box contains 18 tablets in 3X6's Alu-Alu form packs. Each film coated tablet contains Amoxicillin Trihydrate BP equivalent to 500 mg Amoxicillin and Clavulanate Potassium USP equivalent to Clavulanic Acid 125 mg.

Tyclav[®] 1 g Tablet: Each box contains 12 tablets in 2X6's Alu-Alu form packs. Each film coated tablet contains Amoxicillin Trihydrate BP equivalent to 875

mg Amoxicillin and Clavulanate Potassium USP equivalent to Clavulanic Acid 125 mg.

Tyclav[®] Powder for Suspension: Dry powder in a glass bottle for preparation of 100 ml suspension. After reconstitution each 5 ml contains Amoxicillin Trihydrate BP equivalent to Amoxicillin 125 mg and Clavulanate Potassium USP equivalent to Clavulanic Acid 31.25 mg.

Tyclav[®] bid Powder for Suspension: Dry powder in a glass bottle for preparation of 50 ml of suspension. After reconstitution each 5 ml contains Amoxicillin Trihydrate BP equivalent to Amoxicillin 400 mg and Clavulanate Potassium USP equivalent to Clavulanic Acid 57 mg.

Tyclav[®] 0.6 IV Injection: Each combipack contains one vial of sterile mixture of Amoxicillin Sodium equivalent to Amoxicillin 500 mg and Potassium Clavulanate equivalent to Clavulanic Acid 100 mg for Injection BP, one ampoule of water for Injection BP (10 ml) and one disposable syringe (10 ml).

Tyclav[®] 1.2 IV Injection: Each combipack contains one vial of sterile mixture of Amoxicillin Sodium equivalent to Amoxicillin 1 g and Potassium Clavulanate equivalent to Clavulanic Acid 200 mg for Injection BP, one ampoule of water for Injection BP (20 ml) and one disposable syringe (20 ml).

Manufactured by

BEXIMCO PHARMACEUTICALS LTD.

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