

Julmentin

Clavulanate - Potentiated Amoxicillin Film-Coated Tablets, Suspension

Composition

Tablets

Julmentin Forte: Each 625mg tablet contains:

Active ingredients: Amoxicillin trihydrate equivalent to 500mg amoxicillin and potassium clavulanate equivalent to 125mg clavulanic acid.

Excipients: Aerosil, kolidon, magnesium stearate, croscarmellose, cellulose, ethyl cellulose, diethyl phthalate, hypromellose, titanium dioxide, and polyethylene glycol.

Julmentin: Each 375mg tablet contains:

Active ingredients: Amoxicillin trihydrate equivalent to 250mg amoxicillin and potassium clavulanate equivalent to 125mg clavulanic acid.

Excipients: Aerosil, kolidon, magnesium stearate, croscarmellose, cellulose, ethyl cellulose, diethyl phthalate, hypromellose, titanium dioxide, talc, and polyethylene glycol.

Suspension

Julmentin Forte: Each teaspoonful (5mL) of the reconstituted suspension contains:

Active ingredients: Amoxicillin trihydrate equivalent to 250mg amoxicillin and potassium clavulanate equivalent to 62.5mg clavulanic acid.

Excipients: Citric acid, sodium citrate, xanthan gum, sodium benzoate, cellulose, aerosil, saccharin sodium, wild cherry flavour, and mannitol.

Julmentin: Each teaspoonful (5mL) of the reconstituted suspension contains:

Active ingredients: Amoxicillin trihydrate equivalent to 125mg amoxicillin and potassium clavulanate equivalent to 31.25mg clavulanic acid.

Excipients: Citric acid, sodium citrate, saccharin sodium, xanthan gum, sodium benzoate, cellulose, strawberry flavour, aerosil, and mannitol.

Properties

Julmentin is a combination of an aminopenicillin, amoxicillin trihydrate, and a beta-lactamase inhibitor, clavulanic acid. Amoxicillin has a broad-spectrum bactericidal activity against many gram-positive and gram-negative microorganisms; however, it is susceptible to degradation by beta-lactamases. The combination of amoxicillin with clavulanic acid in **Julmentin**, therefore, protects amoxicillin from inactivation by beta-lactamase and effectively extends its spectrum of activity.

Julmentin is effective against the following microorganisms: *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Enterococcus faecalis*, *Streptococcus pneumoniae*, *Corynebacteria*, *Bacillus anthracis*, *Listeria monocytogenes*, *Streptococcus pyogenes*, *Streptococcus viridans*, *Streptococcus agalactiae*, *Clostridia*, *Peptococci*, *Peptostreptococci*, *Haemophilus influenzae*, *Branhamella catarrhalis*, *Enterobacter*, *E. coli*, *Klebsiellae*, *Salmonellae*, *Shigellae*, *Bordetella pertussis*, *Brucellae*, *Proteus mirabilis*, *Proteus vulgaris*, *Neisseria gonorrhoeae*, *Neisseria meningitidis*, *Vibrio cholerae*, *Pasteurella multocida*, *Legionellae*, *Bacteroides*, and *Helicobacter pylori*.

Both components of **Julmentin** are well absorbed after oral administration; food has no effect on the degree of absorption. Peak serum concentration is achieved approximately 1 hour after dosing.

Indications

Julmentin is indicated in the treatment of the following infections when caused by susceptible microorganisms:

- Upper respiratory tract infections (including ENT) e.g. tonsillitis, pharyngitis, sinusitis, and acute otitis media.
- Lower respiratory tract infections including acute and chronic bronchitis and lobar and bronchopneumonia.
- Genito-urinary tract infections such as cystitis, urethritis, pyelonephritis, and chancroid caused by *Haemophilus ducreyi*.
- Skin and soft tissue infections including burn and wound infections, boils, abscesses, and cellulitis.
- Bone and joint infections such as osteomyelitis.
- Other infections including septic abortion, puerperal sepsis, and intra-abdominal sepsis.

Dosage

Adults and Children over 12 years:

Mild to moderate infections: One 375mg tablet every 8 hours for 7-10 days.

Severe infections: One 625mg tablet every 8 hours for 7-10 days.

Chancroid: One 625mg tablet every 8 hours for 3-7 days.

Children 12 years and below:

Dosage usually depends on the severity of the infection. Generally, total daily dose should be divided into 3 equal doses and to be administered for 7-10 days. A recommended regimen is as follows:

Forté suspension:

Children 6-12 years: 5mL (one teaspoonful) every 8 hours or 0.4mL/kg daily in 3 divided doses.

In severe infections, the dose may be increased to 0.8mL/kg daily in 3 divided doses.

Suspension

Children 1-6 years: 5mL (one teaspoonful) every 8 hours.

Infants and Children up to 1 year: 0.8mL/kg daily in 3 divided doses.

In severe infections, the dose may be increased to 1.6mL/kg daily in 3 divided doses.

If you miss a dose

- Take the missed dose as soon as possible.
- If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose.
- Do not take two doses at one time.

Contraindications

It is contraindicated in patients with a known history of allergic reactions to any penicillin as well as in those with a previous history of Julmentin - or penicillin-associated jaundice/ hepatic dysfunction.

Precautions

Patients with a history of sensitivity to cephalosporins or even to multiple allergens are more likely to experience hypersensitivity reactions to Julmentin.

Julmentin should be given cautiously to patients with gastrointestinal diseases since it may lead to pseudomembranous colitis; and to patients with infectious mononucleosis (glandular fever) where there is a high risk to develop erythematous skin rash.

Occasionally, prolonged use may result in overgrowth of non-susceptible organisms.

Patients with impaired renal function should receive a reduced dosage regimen. Caution is advised when using Julmentin in patients with evidence of hepatic dysfunction, as changes in liver function tests have been observed in some patients receiving Julmentin. However, the clinical significance of these changes is uncertain. Rarely; reversible cholestatic jaundice, which may be severe, has been reported. Signs and symptoms may not become apparent for up to six weeks after treatment has ceased.

Pregnancy: As with many other drugs, Julmentin should not be used during pregnancy unless it is clearly needed.

Lactation: Caution should be exercised when Julmentin is given to nursing mothers since it is excreted in the milk.

Side Effects

Julmentin is generally well tolerated, and the side effects are mild and transient in nature including mild gastrointestinal reactions such as diarrhea, nausea and vomiting, as well as skin rashes, urticaria, oral candidiasis, and vaginitis.

Less frequently reported adverse reactions include abdominal discomfort, flatulence, headache, dizziness, and moderate increase in serum transaminase levels.

Overdosage

Since there is no specific antidote, treatment of overdose should be symptomatic. Haemodialysis may aid in the removal of the drug from the blood.

Drug Interactions

Julmentin should not be co-administered with disulfiram.

The concurrent administration of allopurinol and amoxicillin increases substantially the incidence of rashes.

Probenecid decreases the renal tubular excretion of amoxicillin.

Julmentin should be used with care in patients on anticoagulation therapy, as this may lead to prolongation of bleeding time and prothrombin time.

As with other broad-spectrum antibiotics, Julmentin may reduce the efficacy of oral contraceptives and patients should be warned accordingly.

Presentations

Julmentin tablets : Pack of 20 tablets.

Julmentin suspension : Bottle of 100mL.

* Store at room temperature not exceeding 25°C in a dry place, protected from light.

After reconstitution of the suspension, store in a refrigerator and use within 7 days. Shake well before use.

The bottle with tablets must be closed immediately after use.

Note: The desiccant, inserted in the bottle, is not edible.

THIS IS A MEDICAMENT

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of the reach of children.

Council of Arab Health Ministers,
Union of Arab Pharmacists.

Any information? Call Our Toll Free No. (971) 800-4994



Produced by: **Julphar**
Gulf Pharmaceutical Industries,
Ras Al Khaimah, U. A. E.

