

Romycin

Azithromycin Dihydrate USP

Composition:

Romycin 250 Capsule: Each capsule contains Azithromycin 250 mg as Azithromycin Dihydrate USP.

Romycin 500 Tablet: Each tablet contains Azithromycin 500 mg as Azithromycin Dihydrate USP.

Romycin 15 ml Powder for Suspension: After reconstitution each 5 ml suspension contains Azithromycin 200 mg as Azithromycin Dihydrate USP.

Romycin 20 ml Powder for Suspension: After reconstitution each 5 ml suspension contains Azithromycin 200 mg as Azithromycin Dihydrate USP.

Romycin 35 ml Powder for Suspension: After reconstitution each 5 ml suspension contains Azithromycin 200 mg as Azithromycin Dihydrate USP.

Romycin 50 ml Powder for Suspension: After reconstitution each 5 ml suspension contains Azithromycin 200 mg as Azithromycin Dihydrate USP.

Description:

Romycin (Azithromycin) is an azalide antibiotic, a subclass of macrolide antibiotic. It acts by binding with the 50's ribosomal subunit of susceptible microorganisms and thus interfering with microbial protein synthesis. Azithromycin has been shown to be active against most strains of the Gram-positive and Gram-negative microorganisms and in clinical infections of *Staphylococcus aureus*, *Streptococcus agalactiae*, *Streptococcus pyogenes*, *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Moraxella catarrhalis*, *Chlamydia trachomatis* etc. About 40% Azithromycin of an oral dose is absorbed. After oral administration, Azithromycin is rapidly absorbed and widely distributed throughout the body.

Indications and Usage:

Romycin is indicated for the treatment of patients with infections caused by susceptible organisms - **Lower respiratory tract infection** - Acute bacterial exacerbation of chronic obstructive pulmonary disease (COPD), Community acquired pneumonia and Otitis media. **Upper respiratory tract infection** - Acute pharyngitis, tonsillitis. **Gastrointestinal infection** - Cholera, diarrhea, Typhoid/ Enteric fever etc. **Skin and skin structure infections** - Uncomplicated skin and skin structure infections. **Sexually transmitted diseases** - Non-gonococcal urethritis and cervicitis. **Mycobacterial infections** - For prophylaxis, disseminated Mycobacterium avium complex disease.

Dosage and Administration:

Adults - The recommended dose of **Romycin** for the treatment of mild to moderate acute bacterial exacerbations of chronic obstructive pulmonary disease (COPD), pneumonia pharyngitis, tonsillitis and uncomplicated skin and skin structure infections is 500 mg on the first day followed by 250 mg once daily on day 2 to 5. In typhoid fever recommended dose is 1g on day first and 500 mg for the next 6 days or 1g once daily for 5 days. For the treatment of genital ulcer disease 1000 mg single dose & in urethritis and cervicitis is a single dose 2000 mg Azithromycin. **Children dosage:-** In acute otitis media and community-acquired pneumonia of Children above 6 months of age the recommended dose of Azithromycin is 10 mg/kg as a single dose on the first day followed by 5 mg/ kg on day 2-5 (not exceeding 500 mg/day). The recommended dose of Azithromycin for the treatment of children with pharyngitis/tonsillitis is 12 mg/kg once a day for 5 days (not exceeding 500 mg/day. In typhoid/enteric fever dose is 20 mg/kg once daily for 5 days. **Romycin** capsule should be given at least 1 hour before or 2 hours after a meal and tablets can be taken with or without food.

Contraindications:

Azithromycin is contra-indicated in patients with known hypersensitivity to Azithromycin, Erythromycin or any macrolide antibiotic.

Adverse Reactions:

Most reported side effects were mild to moderate severity and reversible upon discontinuation. Transient elevation of liver enzyme values and rarely cholestatic jaundice have been reported. Rash, headache, dizziness may occur, Gastrointestinal side effects are nausea, vomiting, diarrhoea or abdominal pain.

Precautions:

Because Azithromycin is principally eliminated via the liver, thus caution should be exercised when Azithromycin is administered to patients with impaired hepatic functions.

In Pregnancy & Nursing Mother:

Azithromycin should be used during pregnancy only if clearly needed. And it is not known whether Azithromycin is excreted in breast milk, so caution should be exercised when it is administered to a nursing mother.

Drug Interactions:

Azithromycin should be taken at least 1 hour before or 2 hours after taking antacids. Concomitant administration of Ergot derivatives and Azithromycin should be avoided. Caution should be exercised while co-administration of Digoxin and Cyclosporin.

Directions for Reconstitution Suspension:

At first knock the bottle several times to loosen the dry powder. To prepare suspension, add sufficient quantity boiled & cooled water, mentioned in the individual product's label. Add the total water required in two portions. Shake the bottle well in each addition until all the powder is in suspension. Shake the bottle well before use suspension. A cup is supplied to aid water measuring and corrects dosing of suspension. Use within 10 days after reconstitution.

Pharmaceutical Precautions:

Use suspension within 10 days of reconstitution and discard after full dose is completed.

Storage Condition:

• For Capsule & Tablet:

Store below 30° C.

• For Suspension:

Prior to Reconstitution: Store dry powder below 30°C (86°F). Protect from freezing.

After Reconstitution: Store suspension at 5° to 30°C (41°F to 86°F).

How Supplied:

Romycin 250 Capsule: Each box contains 8 (2x4) capsules in Alu-Alu blister pack.

Romycin 500 Tablet: Each box contains 20 (10x2) tablets in Alu-Alu blister pack.

Romycin 15 ml Suspension: Bottle contains dry powder for 15 ml suspension with a measuring cup and dropper.

Romycin 20 ml Suspension: Bottle contains dry powder for 20 ml suspension with a measuring cup and dropper.

Romycin 35 ml Suspension: Bottle contains dry powder for 35 ml suspension with a measuring cup and dropper.

Romycin 50 ml Suspension: Bottle contains dry powder for 50 ml suspension with a measuring cup and dropper.



Manufactured By:
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