
Razithro™

Azithromycin

Composition:

Razithro™ 500 Tablet: Each film coated tablet contains Azithromycin Dihydrate USP equivalent to Azithromycin 500 mg.

Razithro™ Powder for Suspension: After reconstitution of suspension, each 5 ml contains Azithromycin Dihydrate USP equivalent to Azithromycin 200 mg.

Description:

Razithro™ (Azithromycin) is a semisynthetic azalide antibiotic, a subclass of macrolide antibiotics. Azithromycin has a broader spectrum of activity than that of erythromycin. Like other macrolides, Azithromycin binds with the 50s ribosomal subunit of susceptible organisms & thus inhibits the protein synthesis. Azithromycin is active against both gram-positive and gram-negative microorganism.

Indications:

Razithro™ (Azithromycin) is indicated for the treatment of respiratory tract infections, otitis media, skin & soft tissue infections, uncomplicated genital chlamydial infections & non-gonococcal urethritis. Azithromycin is also indicated for the treatment of typhoid fever due to multiple anti-bacterial resistant organisms.

Dosage & administration:

Oral azithromycin should be administered at least 1 hour before or 2 hours after meal.

Adult:

500 mg once daily for 3 days.

Uncomplicated genital chlamydial infections & non-gonococcal urethritis, 1 gm as a single dose.

Typhoid fever, 500 mg to 1 gm once daily for 7 days.

Children:

Child over 6 months, 10 mg/kg once daily for 3 days or

Body weight 15-25 kg, 200 mg once daily for 3 days,

Body weight 26-35 kg, 300 mg once daily for 3 days,

Body weight 36-45 kg, 400 mg once daily for 3 days.

OR AS DIRECTED BY THE PHYSICIAN.

Contra-indications:

Azithromycin is contraindicated in patients with known hypersensitivity to azithromycin.

Warning & precautions:

Azithromycin should be administered with caution in patients with hepatic function impairment because biliary excretion is the major route of elimination for azithromycin. Cautions should be exercised during the administration of azithromycin on neonate under 2 weeks, renal impairment.

Pregnancy: Azithromycin is indicated during pregnancy only if clearly needed.

Lactation: Azithromycin should be administered with caution to a nursing mother.

Side effects:

Nausea, vomiting, abdominal discomfort, diarrhea, constipation, anorexia, dyspepsia, flatulence, pancreatitis, hepatitis, dizziness, drowsiness, headache, anxiety, convulsion, taste disturbance, rashes & other allergic reactions, tongue discoloration etc. may occur.

Drug interactions:

Antacids: In patients receiving azithromycin and antacid, azithromycin should be taken at least 1 hour before or 2 hours after antacid. Cyclosporin & Digoxin: Macrolides interfere with the metabolism of cyclosporin & digoxin. So caution should be exercised before coadministration of these drugs. Ergot derivatives: Because of the theoretical possibility of ergotism, azithromycin and ergot derivatives should not be coadministered. Terfenadine: As with other macrolides, azithromycin should be administered with caution in combination with terfenadine. There have been no pharmacokinetic drug interactions between azithromycin and warfarin, theophylline, carbamazepine, methylprednisolone and cimetidine.

Storage:

Store in a cool and dry place below 30°C, protect from light. Keep out of the reach of children.

Packing:

Razithro™ 500 Tablet: Each box containing 12 tablets in blister packs.

Razithro™ Powder for Suspension: Each bottle containing dry powder for the preparation of 15 ml, 35 ml & 50 ml suspension.

Manufactured by:

Jenphar Bangladesh Ltd.

Sreepur, Gazipur, Bangladesh.