Azaltic

Azithromycin

COMPOSITION

Azaltic 500 Tablet: Each film-coated tablet contains Azithromycin Dihydrate USP equivalent to Azithromycin 500 mg.
Azaltic Powder for Suspension: After reconstitution, each 5 ml suspension contains Azithromycin Dihydrate USP equivalent to Azithromycin 200 mg.

PHARMACOLOGY

Azaltic (Azithromycin) is an azalide antibiotic, subclass of the macrolide antibiotic, active against both Gram-positive and Gram-negative organisms. Azithromycin acts by binding to the ***50S*** ribosomal subunit of susceptible organisms, thus interferes with the microbial protein synthesis.

INDICATIONS

Azaltic (Azithromycin) is indicated for infections caused by susceptible organisms in Lower respiratory tract infections including bronchitis and pneumonia, Skin and soft tissue infections, Otitis media and in Upper respiratory tract infections including sinusitis, pharyngitis and tonsillitis. It is also indicated in the treatment of uncomplicated genital infections due to ***Chlamydia trachomatis*** & typhoid fever.

RECONSTITUTION PROCEDURE OF SUSPENSION:

Step 01: Shake the bottle well to loosen the powder.

Step 02: Add boiled and cooled water up to the water mark of the bottle label.

Step 03: Shake until powder is completely mixed with water.

DOSAGE AND ADMINISTRATION

Adult: 500 mg once daily orally for 3 days or 500 mg once on day 1, then 250 mg once on days 2-5 for 4 days.
For sexually transmitted diseases caused by ***Chlamydia trachomatis*** in adults, the dose is 1 gm given as a single dose or 500 mg once on day 1, followed by 250 mg once daily for next 2 days may also be given.
Children: 10 mg/kg body weight once daily for 3 days for child over 6 months or 200 mg (1 teaspoonful) for 3 days if body weight is 15-25 kg; 300 mg (1½ teaspoonfuls) for 3 days if body weight is 26-35 kg; 400 mg (2 teaspoonfuls) for 3 days if body weight is 36-45 kg.
In Typhoid fever, 500 mg (2½ teaspoonfuls) once daily for 7-10 days is given.
Azaltic (Azithromycin) should be taken at least 1 hour before or 2 hours after meal.

CONTRAINDICATIONS

Azithromycin is contraindicated in patients with known hypersensitivity to Azithromycin or any other macrolide antibiotics. Azithromycin is contraindicated in patients with hepatic diseases.

WARNING & PRECAUTION

Discontinue Azithromycin and initiate appropriate therapy if serious allergic and skin reactions and hepatitis occurs. Prolongation of QT interval and cases of torsades de pointes have been reported. Evaluate patients if *C. difficile* associated diarrhea occurs. It may exacerbate muscle weakness in persons with myasthenia gravis.

SIDE EFFECTS

Azithromycin is well tolerated with a low incidence of side effects. The side effects include nausea, vomiting, abdominal discomfort (pain/cramps), flatulence, diarrhoea, headache, dizziness, and skin rashes.

USE IN PREGNANCY & LACTATION

Pregnancy Category of Azithromycin is B. Animal reproduction studies have demonstrated that Azithromycin has no evidence of harm to the fetus. There are no adequate and well controlled studies in pregnant women. Since animal reproduction studies are not always predictive of human response, Azithromycin should be used during pregnancy only if adequate alternatives are not available. It is not known whether Azithromycin is secreted in breast milk. So, caution should be exercised when Azithromycin is administered to nursing women.

USE IN CHILDREN & ADOLESCENTS

Pediatric Use: Safety and effectiveness in the treatment of patients under 6 months of age have not been established.
Geriatric Use: Elderly patients may be more susceptible to development of torsades de pointes arrhythmias.

DRUG INTERACTIONS

Azithromycin absorption is reduced in presence of food and antacid. In patients receiving ergot alkaloids Azithromycin should be avoided because of the possibility of ergotism resulting from interaction of Azithromycin with the cytochrome P-450 system. As macrolides increase the plasma concentration of digoxin and cyclosporin, caution should be exercised while co-administration. There have been no drug interactions between Azithromycin and Warfarin, Theophylline, Carbamazepine, Methylprednisolone or Cimetidine.

OVERDOSAGE

Adverse reactions experienced in higher than recommended doses were similar to those seen at normal doses. In the event of overdosage, general symptomatic and supportive measures are indicated as required.

STORAGE

Store below 30^{O}C temperature in a cool & dry place. Keep out of the reach of children.

HOW SUPPLIED

Azaltic 500 Tablet: Each box contains 12 tablets in Alu-Alu blister pack.
Azaltic Powder for Suspension: Each amber glass bottle contains dry powder to reconstitute 15 ml & 35 ml suspension.

02026/00

NIPRO JMI Pharma

Manufactured by:
NIPRO JMI Pharma Ltd.
Chauddagram, Cumilla, Bangladesh.