

Azibact

Azithromycin USP

Composition:

Azibact 250 Capsule: Each Capsule contains Azithromycin dihydrate USP equivalent to Azithromycin 250 mg.

Azibact 500 tablet: Each flim coated tablet contains Azithromycin dihydrate USP equivalent to Azithromycin 500 mg.

Azibact powder for suspension: When reconstituted, each 5 ml suspension contains Azithromycin dihydrate USP equivalent to 200 mg Azithromycin.

Pharmacology:

Azibact (Azithromycin) is a semisynthetic azalide antibiotic, a subclass of macrolide antibiotics. Azalides are distinguished from other macrolides by the addition of nitrogen at the lactone ring. This structural modification results in its being resistant to acid degradation, improved tissue penetration, improved activity against gram negative bacteria and a prolonged half-life compared with Erythromycin. Azibact inhibits protein synthesis in susceptible bacteria by penetrating the cell wall and binding to 50s ribosomal subunits, thereby inhibiting polypeptide synthesis.

Indication:

Azibact (Azithromycin) is indicated for the treatment of infections caused by susceptible bacteria.

1. Mild to moderate typhoid fever.
2. Upper respiratory tract infections including pharyngitis, tonsillitis, sinusitis and otitis media; lower respiratory tract infections including bronchitis and pneumonia.
3. Skin and soft tissue infections including acne, cellulitis, pyoderma, wound infections etc.
4. Genital infections including chancroid, gonococcal and nongonococcal urethritis, cervicitis caused by *Chlamydia trachomatis* and uncomplicated gonococcal infections of the cervix, urethra and rectum caused by *Neisseria gonorrhoeae*.
5. Odontogenic infections including dental caries, pulpitis, periapical abscess osteoperiostitis of the jaw, maxillary cysts and periodontal and deep fascial space infections.

Dosage and Administration:

Adults : 500 mg once daily for 3 days

(Typhoid fever: 500 mg - 1 g once daily for 5 - 7 days)

(Acne: 500 mg once daily for 3 days then at 4 days interval for 12 weeks)

Children : Over 6 months : 10 mg / kg once daily for 3 days (Typhoid fever: 20 mg/kg for 5 days)

15-25 kg : 200 mg once daily for 3 days

26-35 kg : 300 mg once daily for 3 days

36-45 kg : 400 mg once daily for 3 days

Contra-indications:

Azithromycin is contraindicated in patients with known hypersensitivity to Azithromycin, Erythromycin or any macrolide antibiotic and with hepatic disease.

Precaution:

Azithromycin should be used with caution in patients with impaired renal function.

Side Effects:

Azithromycin is well tolerated with a low incidence of adverse effects like nausea, vomiting, diarrhoea or abdominal pain.

Use in Pregnancy and Lactation:

The drug should be used during pregnancy only when clearly needed.

Azithromycin has been detected in human milk. The drug should be used with caution in nursing women.

Use in Children and Adolescent:

No studies have showed that Azithromycin causes adverse effects to the children.

Drug Interactions:

Absorption of Azithromycin 500 mg capsule is reduced in presence of food and antacid. So it should be administered 1 hour before or 2 hours after meal. Ergot alkaloids and Azithromycin should be avoided concurrently because of the possibility of ergotism. Macrolides have been known to increase the plasma concentrations of Digoxin and Cyclosporin.

Overdose:

Extreme overdose of Azithromycin may cause liver damage and irregular heart rhythm in the patient. Doctor's consultation is needed in such situation.

Storage:

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

Packing:

Azibact 250 Capsule : Each box contains 2 Alu- Alu blister strips of 3 Capsules.

Azibact 500 tablet : Each box contains 4 Alu- Alu blister strips of 3 tablets.

Azibact powder for suspension: Bottle containing dry powder to prepare 35 ml suspension.



Manufactured by:
Goodman Pharmaceuticals Ltd.
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