

azomac

Azithromycin Tablet / Powder for Suspension

Presentation

Azomac 500 mg Tablet: Each film coated tablet contains Azithromycin USP 500 mg (as Azithromycin Dihydrate).

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

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

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

Indications

Azomac (Azithromycin) is indicated for infections (caused by susceptible organisms) in lower respiratory tract infections including bronchitis and pneumonia, in upper respiratory tract infections including sinusitis and pharyngitis / tonsillitis, in otitis media and in skin and soft tissue infections. In sexually transmitted diseases in men and women, **Azomac** (Azithromycin) is indicated in the treatment of non-gonococcal urethritis and cervicitis due to *Chlamydia trachomatis*.

Dosage & Administration

Azomac can be taken with or without food.

Adults: For lower respiratory tract infections including bronchitis and pneumonia, upper respiratory tract infections including sinusitis and pharyngitis / tonsillitis, otitis media and skin and soft tissue infections the total dose of **Azomac** is 1.5 gm given as 500 mg once daily for 3 days. An alternative to this dosage schedule is that 500 mg once daily on day 1 followed by 250 mg once daily for next 4 days.

For sexually transmitted diseases caused by *Chlamydia trachomatis*, the dose of **Azomac** is 1gm given as a single dose. Alternatively, 500 mg once daily on day 1, followed by 250 mg once daily for next 2 days may also be given.

Use in the elderly: Normal adult dosage is recommended.

Children: The dose of **Azomac** in children over 6 months of age is 10 mg/kg body weight once daily for 3 days. Alternatively, 10 mg/kg on day 1, followed by 5 mg/kg for next 4 days is also recommended. There is no information on use of Azithromycin on children under 6 months of age. For children the dose of **Azomac** suspension is as follows:

Body weight (age)	Dose	Duration
15-25 kg (3-7 years)	200 mg	5 ml daily for 3 days
26-35 kg (8-11 years)	300 mg	7.5 ml daily for 3 days
36-45 kg (12-14 years)	400 mg	10 ml daily for 3 days

For body weights over 45 kg, normal adult dosage is recommended.

Contraindications & Precautions

Azithromycin is contraindicated in patients with a known hypersensitivity to Azithromycin or any other macrolide antibiotics. Because of the theoretical possibility of ergotism, Azithromycin and ergot derivatives should not be co-administered. Azithromycin should not be used in patients with hepatic disease. Avoid concomitant administration with terfenadine or astemizole precaution should be taken in patients with more severe renal impairment.

Side Effects

Azomac (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 and are reversible upon discontinuation of therapy.

Drug Interactions

Antacids: Peak serum levels but not the total extent of absorption are reduced by aluminum and magnesium containing antacids in the stomach. Azithromycin should therefore be taken at least 1 hour before or 2 hours after taking these antacids. **Ergot derivatives:** Because of the theoretical possibility of ergotism, concomitant administration of ergot derivatives and Azithromycin should be avoided. **Digoxin & Cyclosporin:** Macrolides have been known to increase the plasma concentration of Digoxin & Cyclosporin and so caution should be exercised while co-administration is necessary.

Use in Pregnancy and Lactation

Recent clinical studies have recommended that Azithromycin should be considered for the initial treatment of chlamydial cervicitis in pregnancy. In other infections, Azithromycin should be used only when clearly needed. It is not known whether Azithromycin is excreted in breast milk. Exercise caution when administering to nursing women.

Storage Conditions

Store in a cool and dry place protected from light. Keep out of children's reach.

Commercial Pack

Azomac 500 mg Tablet: Each box contains 3 Alu-Alu blister packs of 4 tablets.

Azomac 15 ml Powder for Suspension: Each bottle contains dry powder for preparation of 15 ml suspension.

Azomac 35 ml Powder for Suspension: Each bottle contains dry powder for preparation of 35 ml suspension.

Azomac 50 ml Powder for Suspension: Each bottle contains dry powder for preparation of 50 ml suspension.

Manufactured by :

 **GENERAL**
Pharmaceuticals Ltd.
Gazipur, Bangladesh

