

Orgazith™

Azithromycin

PRESENTATION:

Orgazith™ 250 Capsule : Each capsule contains Azithromycin Dihydrate USP equivalent to Azithromycin 250 mg.

Orgazith™ 500 Tablet : Each tablet contains Azithromycin Dihydrate USP equivalent to Azithromycin 500 mg.

Orgazith™ 20 ml Powder for Suspension : After reconstitution, each 5 ml suspension contains Azithromycin Dihydrate USP equivalent to Azithromycin 200 mg.

Orgazith™ 35 ml Powder for Suspension : After reconstitution, each 5 ml suspension contains Azithromycin Dihydrate USP equivalent to Azithromycin 200 mg.

Orgazith™ 50 ml Powder for Suspension : After reconstitution, each 5 ml suspension contains Azithromycin Dihydrate USP equivalent to Azithromycin 200 mg.

INDICATIONS:

Orgazith™ is indicated for the treatment of infections caused by susceptible organisms e.g. Lower Respiratory Tract infections including Bronchitis and Pneumonia, Skin & Soft Tissue infections, Otitis Media and in Upper Respiratory Tract infections including Sinusitis, Pharyngitis and Tonsillitis. In Sexually Transmitted Diseases in men & women. Azithromycin is also indicated for the treatment of uncomplicated genital infections due to Chlamydia trachomatis.

DOSAGE & ADMINISTRATION:

Orgazith™ 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 Orgazith™ 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 Orgazith™ 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 Orgazith™ 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 Orgazith™ 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.

SIDE EFFECTS:

Azithromycin is well tolerated with a low incidence of adverse effects. The majority of effects are gastrointestinal in origin with nausea, abdominal discomfort, vomiting, flatulence, diarrhea and loose stools being occasionally observed.

CONTRA INDICATIONS:

Azithromycin is contraindicated in patients with known hypersensitivity to Azithromycin or any other macrolide antibiotics. Because of theoretical possibility of ergotism. Azithromycin and ergot derivatives should not be co-administered.

PRECAUTIONS:

Because Azithromycin is principally eliminated via liver, so caution should be exercised when Azithromycin is administered in patients with impaired hepatic function. No dose adjustment is needed for the patients with mild renal impairment (creatinine clearance >40 ml per min) but there is no data regarding Azithromycin usage in patients with more severe renal impairments, thus caution should be exercised in using Azithromycin in those patients.

USE IN PREGNANCY & LACTATION:

There are no adequate and well controlled studies in pregnant women. Azithromycin should be used during pregnancy only if alternatives are not available. No data on secretion of Azithromycin in breast milk are available. So Azithromycin should be used in lactating women where alternatives are not available.

DRUG INTERACTIONS:

In patients receiving Azithromycin and Antacid, Azithromycin should be taken at least 1 hour before or 2 hours after Antacid (Because Antacid decrease the serum level of Azithromycin). Caution should be exercised before co-administered of Azithromycin and Cyclosporine. No significant drug interaction is found.

STORAGE:

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

PACKING:

Orgazith™ 250 Capsule: Box containing 2 x 6 capsules in Alu-Alu blister strip.

Orgazith™ 500 Tablet: Box containing 3 x 4 tablets in Alu-Alu blister strip.

Orgazith™ 20 ml Powder for Suspension: Each bottle contains dry powder to reconstitute 20 ml suspension.

Orgazith™ 35 ml Powder for Suspension: Each bottle contains dry powder to reconstitute 35 ml suspension.

Orgazith™ 50 ml Powder for Suspension: Each bottle contains dry powder to reconstitute 50 ml suspension.

Manufactured by:

Organic Health Care Ltd.
Gazipur, Bangladesh.

