

AZOGIL Capsules
250mg
(Azithromycin) Tablets
500mg
Antibiotic

ایزوگل
ازیترومایسین
۲۵۰ ملی گرام
کپسولز
۵۰۰ ملی گرام
گولیاں

Presentations:

Each capsule contains:

Azithromycin dihydrate USP Equivalent to 250 mg of Azithromycin.

Each Tablets contains:

Azithromycin dihydrate USP Equivalent to 500 mg of Azithromycin.

Properties:

Azithromycin is Azolide derived from the macrolide class of antibiotics.

Azithromycin demonstrates activity invitro, against a wide range of Gram-positive and Gram-negative bacteria including Staphylococcus aureus, Streptococcus pneumoniae, Streptococcus pyogenes (Group A) and other Streptococcal species; Haemophilus influenzae and para-influenzae; Moraxella catarrhalis; anaerobes including Bacteroides fragilis; Escherichia coli; Bordetella pertussis; Bordetella parapertussis; Borrelia burgdorferi; Haemophilus ducreyi; Neisseria gonorrhoea and Chlamydia trachomatis, Azithromycin also demonstrates in-vitro activity against legionella pneumophila; Mycoplasma pneumoniae and hominis; Campylobacter sp.; Toxoplasma gondii and Treponema pallidum.

Pharmacokinetics:

Following oral administration in humans, azithromycin is widely distributed throughout the body: bioavailability is approximately 37%. The time taken to reach peak plasma levels is 2-3 hours. Plasma terminal elimination half-life closely reflects the tissue depletion half-life of 2 to 4 days. Kinetic studies have shown markedly higher azithromycin levels in tissue than in plasma (upto 50 times the maximum observed concentration in plasma) indicating that the drug is highly tissue bound.

Concentrations in target tissue such as lungs, tonsils and prostate exceed the MIC90 for likely pathogens after a single dose of 500mg.

Indications:

Azithromycin is indicated for infection 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 and pharyngitis/tonsillitis.

Sexually transmitted diseases in men and women, azithromycin is indicated in the treatment of uncomplicated genital infections due to Chlamydia trachomatis.

Dosage and administration: Azithromycin should be administered as single dose, and as common with many other antibiotics, should be taken at least 1 hour before or 2 hours after food.

Adults:

For all indications except sexually transmitted diseases, the total dose is 1.5 g which should be given as 500 mg as a single dose daily for 3 days alternatively an initial dose of 500 mg in the first day may be followed by 250 mg daily for further 4 days. For sexually transmitted diseases caused by Chlamydia trachomatis the dose is 1 g given as a single dose.

Use in children:

There is no information on children under six months of age. The dose in children is 10 mg/kg as a single daily dose for 3 days.

Contra-indications:

Azithromycin is contra-indicated in patients with a known hypersensitivity to azithromycin or any macrolide antibiotics.

Because of the theoretical possibility of ergotism, azithromycin and ergot derivatives should not be co-administrated.

Side-effects:

Azithromycin is well tolerated with low incidence of side effects. Most side-effects observed were mild-to moderate in severity.

Age (Yrs)	Weight(kg)	Dosage (10mg/kg)
0.5-2.0	4.5-12.0	1.5-3ml(45-120mg)
2.5-4.0	14.0-16.0	3.5-4ml(140-160mg)
4.5-6.0	17.0-20.5	4.5-5ml(170-205mg)
6.5-8.0	21.5-25.0	5.0-6.5ml(215-250mg)
8.5-10.0	26.5-31.0	6.5-8ml(265-310mg)
10.5-12.0	33.0-40.0	8.5-10.5ml(330-400mg)
12.5-14.0	41.0-50.5	11-12.5ml(410-505mg)
14.5-16.0	52.0-62.0	13.5-15.5ml(520-620mg)
16.5-18.0	64.0-69.0	16-17ml(640-690mg)

The majority of side-effects were of gastrointestinal origin with nausea, abdominal discomfort (pain/cramps), Vomiting, flatulence, diarrhoea and loose stools being occasionally observed.

Allergic reactions such as rashes have occurred and there have been rare reports of serious hypersensitivity reactions. Reversible elevations in liver transaminases have been seen with a frequency similar to the comparative macrolides and penicillins used in clinical trials. Transient mild reductions in neutrophil counts have occasionally been observed in clinical trials, although a casual relationship to azithromycin has not been established.

Overdosage:

There is no data on overdosage with azithromycin.

Typical symptoms of overdosage with macrolide antibiotics include hearing loss, severe nausea, vomiting and diarrhoea. Gastric lavage and general supportive measures are indicated.

Dose:

Use as prescribed by the physician.

Precautions:

Store at room temperature.

Keep away from children.

Protect from direct sunlight, heat and moisture..

Pack Size:

2 x 5's capsules blister.

1x6's Tablets blister.

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