# AZIROM

250mg Tablets
Oral Suspension

Azithromycin

ایزی روم

(ایزی تھرومائی سین)

**COMPOSITION:**
Each Tablet contains Azithromycin dihydrate U.S.P equivalent to 250mg of azithromycin (Base).
Each 5ml oral suspension contains Azithromycin dihydrate U.S.P equivalent to 200mg of azithromycin (Base).

**PROPERTIES:**
Azithromycin is an azalide, derived from the macrolide class of antibiotics. Azithromycin demonstrates activity in vitro against a wide range of Gram-positive and Gram-negative bacteria including, Staphylococcus aureus, Streptococcus pneumonia, Streptococcus pyogenes (Group A) and other Streptococcal species; Haemophilus infuenzae and haemophilus parainfluenzae; Moraxella catarrhalis, anaerobes including Bacteroides fragillis; Escherichia coli; Borderella pertussis; Bordetella paraper tussis; Borrelia burgdoferi; Haemophilus ducrey; Neisseria gonorrhoeae and Chlamydia trachomatis. Mycoplasma, pneumoniae and Mycoplasma hominis, Campylobacter spp, Toxoplasma gondii and Treponema, pallidum.

**PHARMACOKINETICS:**
Following oral administration in humans, azithromycin is widely distributed throughout the body. Bioavailability is approximately 37%. Time taken to reach peak plasma levels is 2 to 4 days. Kinetic studies have shown markedly higher azithromycin levels in tissue than in plasma (up to 50 times the maximum observed concentration in plasma.

**INDICATIONS:**
Azirom (Azithromycin) is indicated for infections caused by the susceptible organisms.
Upper and lower respiratory tract infections; Otitis media, pharyngitis, tonsillitis, uncomplicated skin and skin structure infections due to Staphylococcus aureus, Streptococcus pyogenes, or Streptococcus agalactiae. Abscesses usually require surgical drainage,
urethritis and cervicitis due to Chlamydia trachomatis or Neisseria gonorrhoeae. Genital ulcer disease in men due to Haemophilus ducreyi (Chancroid).
Azithromycin is indicated as second line therapy for typhoid fever caused by Salmonella typhi and Salmonella paratyphi.

**DOSAGE AND ADMINISTRATION:**
AZIROM (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 respiratory tract infections and skin and soft tissue infections, the total dose is 1.5 gram which should be given as 500mg as a single dose daily for 3 days. Alternatively an initial dose of 500mg on the first day may be followed by 250mg daily for further 4 days. For sexually transmitted diseases caused by Chlamydia trachomatis, the dose is 1000mg given as a single dose. For typhoid fever the dose is 500mg to 1000mg oncd daily for 5 to 7 days.
Children: There is no information on children under six months of age. The dose i children is 10mg per Kg as a single daily dose for 3 days. for typhoid fever therapy, should be given for 7 days.

**CONTRAINDICATIONS:**
Azithromycin is contraindicated in patients with known hypersensitivity to azithromycin or any macrolide antibiotic.

**PRECAUTIONS AND WARNINGS:**
As with any antibiotic, observation for signs of superinfection with non-susceptible organisms including fungi is recommended. As with erythromycin and other macrolides, serious sallergic reactions including angioneurotic oedema and anaphylaxis have been reported. Some of these reactions with azithrmycin have resulted in recurrent symptoms and required a long period of observation and treatment.

**USE IN RENAL IMPAIRMENT:**
No dosage adjustment is needed inpatients with mild renal impairment (creatinine clearance>40 ml/min.) but there are no data regarding azithromycin usage in patients with more severe renal impairment, thus caution should be exercised in using aztithromycin in these patients.

**USE IN HEPATIC IMPAIRMENT:**
As liver is the principal route of excretion of azithromycin, it should not be used in patients with hepatic disease.

**USE IN PREGNANCY:**
Animal reproduction studies have demonstrated that azithromycin crosses the placenta but have revealed no evidence of harm to the fetus. Their are no adequate and well controlled studies in pregnant women. Since animal reproduction dtudies are not always preductive of human response. Azithromycin should be used during pregnancy only ir adequate alternative area not available.

**USE IN LACTATION:**
No data o secretion of azithromycin in breast milk are available, so azithromycin should only be used in lactating women where adequate alternatives are no available.

**DRUG INTERACTIONS:**
**Antacids:** In patients receiving azithromycin and antacids, azithromycin should be taken at least 1 hour before or 2 hours after the antacid.
**Carbamazepine:** No significant effect was observed on the plasma levels of carbamazepine or its active metabolite.
Cyclosporin: Some of the related macrolide antibiotics interfere with the metablisim of cyclosporin. caution should be exercised before co-administration of these two drugs.
**Digoxin:** No interaction have been reported in patients who have received concomitant azithromycin and cardiac glycosides. However some of the macrolides antibiotics have been reported to impair the metabolism of digoxin in the gut in some patients. Therefore in patiences. Therefore in patients receiving concomitant azithromycin and digoxin, the possibility of raised digoxin levels should be kept in mind.
**Ergot derivatives:** Because of the theoretical possibility of egotism, azithromycin and ergot derivatives should not be co-administrated.
Warfarin: In a pharmacokinetics interaction study azithromycin did not alter the anticoagulant effect of single 15mg dose of warfarin administered in healthy volunteers. Azithromycin and warfarin may be co-administrated but monitoring of the prothrombin time should be continued as routinely performed.

**SIDE EFFECTS:**
Azithromycin is well tolerated with a low incidence of side effects. Most side effects observed were mild to moderate in severity. The majority of side effects were of gastrointestinal origin with nausea, abdominal discomfort, vomiting, flatulence and diarrhea. Allergic reactions such as rashed have occurred and there have also been rare reports of serous hypersensitivity reactions. Reversible comparative macrolides and penicillins used in clinical trials. Transient mild reductions in neutrophil counts have occasionally been observed in clinical trials, although a causal relationship to azithromycin has not been established.

**OVERDOSAGE:**
Most adverse events experienced in higher then recommended doses were similar in type and may be more frequent than those seen at normal doses. The incidence of tinnitus and toxicity is more frequent in overdosage than at normal doses. In the event of overdosage, general symptomatic and supportive measures are indicated as required.

**STORAGE:**
Protect from heat, light and moisture.
Warming: All drugs should be kept out of the reach of children.

**PRESENTATION:**
Azirom Tablets: 6 tablets of 250mg each in Alu-Alu blister pack.
Azirom suspension: 200mg per 5ml granules for 15ml oral suspension.

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
ہدایت: ٹھنڈی اور خشک جگہ پر بچوں کی پہنچ سے دور رکھیں۔
اور سورج کی روشنی سے بچائیں۔

Macquin's
Manufactured by:
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