Zithrin®

Tablet/Capsule/Suspension

Azithromycin USP

DESCRIPTION: Zithrin® contains Azithromycin. It is an Azalide, a subclass of macrolide antibiotics active against Gram-positive and Gram-negative organisms. Azithromycin is derived from Erythromycin. Azithromycin interferes with ribosome function in susceptible bacteria by inhibiting the translocation of peptides.

INDICATIONS: Zithrin® is indicated for infections 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, pharyngitis and tonsillitis.
Zithrin®(Azithromycin) is indicated in the treatment of uncomplicated genital infections due to *Chlamydia trachomatis*.
Zithrin®(Azithromycin) is also indicated in enteric fever, diarrhoea and cholera.

DOSAGE AND ADMINISTRATION: For Adults, Zithrin®(Azithromycin) should be given as 500mg once daily orally for 3 days or as an alternative given over 5 days with 500mg on day 1 then 250mg on days 2-5.
For sexually transmitted diseases caused by *Chlamydia trachomatis* in adults, the dose is 1g given as a single dose.
For complicated enteric fever, in adults 1g of Azithromycin and in children 20mg/kg of Azithromycin once daily for 5 days can be given.
For diarrhoea, in adults 500mg of Azithromycin and in children 10mg/kg of Azithromycin once daily for 3 days can be given.
For cholera, in adults 1g a single dose of Azithromycin and in children 20mg/kg a single dose of Azithromycin can be given.
Normal adult dose is recommended for elderly patients.
For children over 1 month recommended dose is 10mg/kg once daily for 3 days; or if body weight is 15-25kg: 200 mg once daily for 3 days; body weight is 26-35kg: 300mg once daily for 3 days, body weight is 36-45kg: 400mg once daily for 3 days. Azithromycin is also preferred for infant below 1 month, though limited safety data are available.
As common with many other antibiotics, Zithrin® should be taken at least 1 hour before or 2 hours after meal and antacid.

CONTRAINDICATIONS: Azithromycin is contraindicated in patients hypersensitive to Azithromycin or any other macrolide antibiotic. Co-administration of ergot derivatives and Azithromycin is contraindicated. Azithromycin is contraindicated in patients with hepatic diseases.

SIDE EFFECTS: Azithromycin is well tolerated with a low incidence of side effects. Majority of the side effects were mild to moderate in nature and of gastrointestinal in origin with nausea, abdominal discomfort, vomiting, flatulence and diarrhoea. Allergic reactions such as rash have occurred and there have also been rare reports of serious hypersensitivity reactions. Reversible elevations in liver transaminases have been seen with a frequency similarly 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 causal relationship to Azithromycin has not been established.

PRECAUTIONS: As with any antibiotic, observation for signs of super infection with no susceptible organisms, including fungi recommended. No dose adjustment is needed in patients with renal impairment.

USE IN PREGNANCY AND LACTATION: Animal reproduction studies have demonstrated that Azithromycin crosses the placenta, but have revealed no evidence of harm to the fetus. There are no adequate and well-controlled studies in pregnant women. Since animal reproduction studies are not always predictive of human response, Azithromycin should be used during pregnancy only, if adequate alternatives are not available. No data on secretion of Azithromycin in breast milk is available. So, Azithromycin should only be used in lactating women where adequate alternatives are not available.

DRUG INTERACTIONS: Azithromycin absorption was reduced in presence of food and antacid. So, Azithromycin should be administered 1 hour before or 2 hours after taking food or antacid. In patients receiving ergot alkaloids Azithromycin should be avoided concurrently because of the possibility of ergotism resulting from interaction of Azithromycin with the cytochrome P-450 system. However, no cases of such interaction have been reported. Macrolides have been known to increase the plasma concentration of digoxin and Cyclosporin. Therefore, if co-administration is necessary, caution should be exercised and serum level of digoxin and Cyclosporin should be checked. There have been no pharmacokinetic drug interactions between Azithromycin and warfarin, Theophylline, Carbamazepine, Methylprednisolone and Cimetidine.

Potentially life-threatening torsades de pointes arrythmia has been reported in-patient on Astimizole and Erythromycin. Other macrolides (Clarithromycin, Troleandomycin) are believed to interact similarly but not Azithromycin.

Erythromycin causes terfenadine to accumulate in a few individuals, which can prolong the QT interval in those with apparently normal cardiac function increasing the risk of life threatening torsades de pointes arrhythmias. Clarithromycin and Troleandomycin appear to interact similarly but not Azithromycin.

Erythromycin and Clarithromycin can increase the serum levels of cisapride, resulting in a prolongation of the QT interval and increasing the risk of serious venticular arrhythmias including torsades de points. The concurrent use of these macrolides and cisapride is contraindicated. Troleandomycin is predicted to interact similarly but probably not Azithromycin.

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.

STORAGE CONDITIONS: Store in a cool and dry place, away from light and children.

HOW SUPPLIED:
500mg Tablet : Box containing 2x6, 3x5 tablets in alu-alu blister strips, each tablet contains Azithromycin Dihydrate equivalent to 500mg Azithromycin.

250mg Tablet : Box containing 2x6, 3x5 tablets in alu-alu blister strips, each tablet contains Azithromycin Dihydrate equivalent to 250mg Azithromycin.

250mg Capsule: Box containing 2x6 capsules in alu-alu blister strips, each capsule contains Azithromycin Dihydrate equivalent to 250mg Azithromycin.

15ml Suspension: Dry powder in glass bottle for reconstitution into 15ml of suspension. After reconstitution each 5ml contains Azithromycin Dihydrate equivalent to 200mg Azithromycin.

20ml Suspension: Dry powder in glass bottle for reconstitution into 20ml of suspension. After reconstitution each 5ml contains Azithromycin Dihydrate equivalent to 200mg Azithromycin.

30ml Suspension: Dry powder in glass bottle for reconstitution into 30ml of suspension. After reconstitution each 5ml contains Azithromycin Dihydrate equivalent to 200mg Azithromycin.

35ml Suspension: Dry powder in glass bottle for reconstitution into 35ml of suspension. After reconstitution each 5ml contains Azithromycin Dihydrate equivalent to 200mg Azithromycin.

50ml Suspension: Dry powder in glass bottle for reconstitution into 50ml of suspension. After reconstitution each 5ml contains Azithromycin Dihydrate equivalent to 200mg Azithromycin.

® Trade Mark

Manufactured by
Renata Limited
Mirpur, Dhaka, Bangladesh

Tablet (250mg & 500mg), Capsule (250mg)
Suspension (15ml, 20ml, 30ml, 35ml & 50ml)

Manufactured by
Renata Limited
Rajendrapur, Gazipur, Bangladesh.

Tablet (250mg & 500mg)