

ZEECIN

COMPOSITION:

Zeecin 250mg Tablets

Each film coated tablet contains:

Azithromycin (as Dihydrate) U.S.P250mg

Zeecin 500mg Tablets

Each film coated tablet contains:

Azithromycin (as Dihydrate) U.S.P500mg

Zeecin 200mg/5ml Suspension

Each 5ml contains:

Azithromycin (as Dihydrate) U.S.P200mg

Zeecin 500mg Injection

Each vial contains:

Azithromycin.....500mg

Product conforms to U.S.P Specifications.

DESCRIPTION:

Azithromycin (Zeecin) contains Azithromycin U.S.P.

It is a nitrogen containing macrolide or azolide for oral administration

with a chemical formula of $C_{38}H_{72}N_2O_{12} \cdot 2H_2O$ and a molecular weight of 785.0.

CLINICAL PHARMACOLOGY:

Azithromycin (Zeecin) acts by binding to the 50 S ribosomal subunit of susceptible organisms and thus interfering with microbial protein synthesis.

Following oral administration, Azithromycin is rapidly absorbed and widely distributed throughout the body. Absorption is reduced by food. Peak plasma concentrations are achieved in 2-3 hours after a dose. Rapid distribution of Azithromycin into tissues and high concentrations within cells results in significantly higher Azithromycin concentration in tissues than in plasma or serum. Only very low concentrations were noted in CSF (Less than 0.01 mcg / ml) in the presence of non-inflamed meninges. The serum protein binding of Azithromycin is variable in the concentration range approximating human exposure, decreasing from 51% at 0.02 mcg / ml to 7% at 2 mcg / ml.

Biliary excretion of Azithromycin, predominantly as unchanged drug, is a major route of excretion over the course of a week, approximately 6% of the administered dose appears as unchanged drug in urine.

INDICATIONS:

Azithromycin (Zeecin) is active against both Gram positive and Gram negative organisms. It is indicated for the treatment of infections caused by susceptible bacteria in conditions listed below:

Upper Respiratory Tract Infection: Acute Pharyngitis, Acute Tonsillitis, Sinusitis and Acute Otitis media.

Lower Respiratory Tract Infections: Acute bronchitis, Acute bacterial exacerbations of Chronic Obstructive Pulmonary Disease (COPD) and Pneumonia.

Uncomplicated Skin and Skin Structure Infections: Due to Staphylococcus aureus, Streptococcus pyogenes, or Streptococcus agalactiae. Abscesses usually require surgical drainage.

Genitourinary Infections: Infections due to Chlamydia trachomatis like Nongonococcal Urethritis and Cervicitis.



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DOSAGE AND ADMINISTRATION:

Since food reduces the absorption of Azithromycin (Zeeцин), it should be given one hour before or two hours after meal.

Adult Dose:

Azithromycin (Zeeцин) 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 250 mg on 2-5 days.

For sexually transmitted diseases caused by *Chlamydia trachomatis* in adults, the dose is 1 g given as a single dose.

Normal adult dose is recommended for elderly patients.

Children Dose:

For Children over 6 months recommended dose is 10mg / kg once daily for 3 days or if body weight is 15-25 kg: 200mg once daily for 3 days, body weight is 26-35 kg: 300mg once daily for 3 days, body weight is 36-45 kg: 400mg once daily for 3 days.

Alternative regimen is 10mg / kg on day 1, followed by 5mg / kg from day 2 to day 5.

CONTRAINDICATIONS:

Azithromycin (Zeeцин) 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.

ADVERSE DRUG REACTIONS:

Azithromycin (Zeeцин) 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 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 causal relationship to Azithromycin (Zeeцин) has not been established.

PRECAUTIONS:

s with any antibiotic, observation for signs of superinfection with nonsusceptible organisms, including Fungi, is recommended.

No dose adjustment is needed in patients with renal impairment.

USE IN PREGNANCY AND LACTATION:

Animal reproduction studies have demonstrated that Azithromycin (Zeeцин) crosses the placenta, but have revealed no evidence of harm to the foetus. There are no adequate and well controlled studies in pregnant women. Since animal reproduction studies are not always predictive of human response, Azithromycin (Zeeцин) 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 (Zeeцин) should only be used in lactating women where adequate alternatives are not available.



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DRUG INTERACTION:

Azithromycin (Zeecin) absorption was reduced in presence of food and antacid. So, Azithromycin (Zeecin) should be administered 1 hour before or 2 hours after taking food or antacid. In patients receiving Ergot alkaloids, Azithromycin (Zeecin) should be avoided concurrently, because of the possibility of ergotism resulting from interaction of Azithromycin (Zeecin) 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 coadministration 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 (Zeecin) and Warfarin, Theophylline, Carbamazepine, Methylprednisolone and Cimetidine.

OVER DOSAGE:

There is no data on overdosage with Azithromycin (Zeecin). Typical symptoms of overdosage with macrolide antibiotics include hearing loss, severe nausea, vomiting and diarrhoea. Gastric lavage and general supportive measures are indicated.

INSTRUCTIONS:

Store in a cool & dry place below 25°C.
Protect from light, heat and moisture.
Keep out of reach of children.

PRESENTATION:

Zeecin 250mg tablets are available in a blister pack of 6's
Zeecin 500mg tablets are available in a blister pack of 3's
Zeecin 200mg/5ml suspension is available in bottle of 15ml
Zeecin 500mg IV Injection is available in pack of 1's

