

Zycin

Azithromycin USP

PRESENTATION

Zycin-500 Tablet: Each film coated tablet contains Azithromycin Dihydrate USP equivalent to Azithromycin 500 mg.

Zycin Dry Powder for 15 ml, 30 ml & 50 ml Suspension: Each 5 ml reconstituted suspension contains Azithromycin Dihydrate USP equivalent to Azithromycin 200 mg.

INDICATION

Azithromycin is indicated for the treatment of infections caused by susceptible microorganisms in the specific conditions listed below.

Acute bacterial exacerbations of chronic obstructive pulmonary disease, Acute bacterial sinusitis, Community-acquired pneumonia, Pharyngitis, Tonsillitis, Acute otitis media, Uncomplicated skin and skin structure infections, Diarrhea, Typhoid fever, Urethritis and Cervicitis due to *Chlamydia trachomatis* or *Neisseria gonorrhoeae* and other Sexually transmitted disease.

DOSAGE AND ADMINISTRATION

Zycin tablet and oral suspension can be taken with or without food.

Adults

Azithromycin should be taken as 500 mg once daily for 3 days or as an alternative, taken over 5 days with 500 mg on day 1, then 250 mg once daily on days 2-5. For sexually transmitted diseases caused by *Chlamydia trachomatis*, the dose of Azithromycin is 1 gm given as a single dose. Alternatively, 500 mg on day 1, then 250 mg once daily on days 2-3.

Elderly

Normal adult dose is recommended.

Children

For children over 6 months, the recommended dose is 10 mg/kg body weight once daily for 3 days. There is no information on children under six months of age.

Direction For Suspension Preparation

Shake the bottle until all powder flows freely. Add the boiled and cooled water as per following chart and shake vigorously to make oral suspension.

Preparation	Water to be added
Zycin 15 ml	10 ml
Zycin 30 ml	20 ml
Zycin 50 ml	35 ml

CONTRAINDICATIONS AND PRECAUTION

Zycin is contraindicated in patients with a known hypersensitivity to Azithromycin or any of the macrolide antibiotics. Co-administration of ergot derivatives and Azithromycin is contraindicated. Azithromycin should not be used in patients with hepatic disease. Avoid concomitant administration with terfenadine or astemizole. Precaution should be taken in patients with more severe renal impairment.

SIDE EFFECT

Zycin is well tolerated with a low incidence of side effects. The side effects include nausea, vomiting, abdominal discomfort (pains/cramps), flatulence, diarrhea, headache, dizziness & skin rashes and are reversible upon discontinuation of therapy.

OVERDOSE

There are no data on overdoses with Azithromycin. Typical symptoms with macrolide antibiotics include hearing loss, severe nausea, vomiting and diarrhea. Gastric lavage and general supportive measures are indicated.

DRUG INTERACTION

Zycin should be administered at least 1 hour before or 2 hours after antacid taken. In-patient 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.

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, Zycin should be used during pregnancy only if adequate alternatives are not available. No data on secretion of Azithromycin in breast milk is available, so Zycin should only be used in lactating mothers where adequate alternatives are not available. Caution Should be exercised when Azithromycin is administered to nursing mother.

STORAGE

Store in a cool & dry place, away from light & Keep out of reach of children.

COMMERCIAL PACK

Zycin-500 Tablet: Each box contains 2 x 6 tablets in alu-alu blister strips.

Zycin 15 ml Powder for Suspension: Box containing bottle of dry powder for 15 ml suspension.

Zycin 30 ml Powder for Suspension: Box containing bottle of dry powder for 30 ml suspension.

Zycin 50 ml Powder for Suspension: Box containing bottle of dry powder for 50 ml suspension.

Manufactured by:



Globe Pharmaceuticals Ltd.

Noakhali, Bangladesh.