

Telide[®]

Azithromycin

COMPOSITION:

Telide[®] 500 Tablet: Each film coated tablet contains Azithromycin Dihydrate USP equivalent to Azithromycin 500 mg.

Telide[®] Powder for Suspension: Each 5 ml suspension contains Azithromycin Dihydrate USP equivalent to Azithromycin USP 200 mg.

PHARMACOLOGY:

Azithromycin is a semisynthetic azalide antibiotic, a subclass of macrolide antibiotics. Azithromycin has a broader spectrum of activity than that of Erythromycin. Like other macrolides, Azithromycin binds with the 50s ribosomal subunit of susceptible organisms & thus inhibits the protein synthesis. Azithromycin is active against both gram-positive and gram-negative bacteria.

INDICATION:

Azithromycin is indicated for the treatment of respiratory tract infections, otitis media, skin & soft tissue infections, uncomplicated genital chlamydial infections & non-gonococcal urethritis.

Azithromycin is also indicated for the treatment of typhoid fever due to multiple- antibacterial-resistant organisms.

DOSE & ADMINISTRATION:

Oral Azithromycin should be administered at least 1 hour before or 2 hours after meal. Adult: 500 mg once daily for 3 days. Uncomplicated genital chlamydial infections & non-gonococcal urethritis: 1 gm as a single dose. Typhoid fever: 500 mg to 1 gm once daily for 7 days. Children: Child over 6 months, 10 mg/kg once daily for 3 days or Body weight 15-25 kg, 200 mg once daily for 3 days, Body weight 26-35 kg, 300 mg once daily for 3 days, Body weight 36-45 kg, 400 mg once daily for 3 days. Or as Directed by the Physician.

Preparation of suspension: To reconstitute Telide[®] 15 ml, 35 ml & 50 ml powder for suspension, add 10 ml, 25 ml & 35 ml of just boiled & cooled water respectively to the content of the bottle and shake well to mix uniformly.

CONTRA-INDICATION:

Azithromycin is contraindicated in patients with known hypersensitivity to Azithromycin.

WARNING & PRECAUTION:

Azithromycin should be administered with caution in patients with hepatic function impairment because biliary excretion is the major route of elimination for Azithromycin. Cautions should be exercised during the administration of Azithromycin on neonate under 2 weeks, renal impairment.

SIDE EFFECTS:

Nausea, vomiting, abdominal discomfort, diarrhea, constipation, anorexia, dyspepsia, flatulence, pancreatitis, hepatitis, dizziness, drowsiness, headache, anxiety, convulsion, rashes & other allergic reactions, tongue discoloration etc. may occur.

USE IN PREGNANCY & LACTATION:

Azithromycin is indicated during pregnancy only if clearly needed.

Use during lactation: Azithromycin should be used with caution in mothers during lactation.

USE IN CHILDREN AND ADOLESCENTS:

Safety and effectiveness in the treatment of pediatric patients with acute otitis media, acute bacterial sinusitis and community-acquired pneumonia under 6 months of age have not been established. Use of Azithromycin for the treatment of acute bacterial sinusitis and community-acquired pneumonia in pediatric patients (6 months of age or greater) is supported by adequate and well-controlled trials in adults.

Pharyngitis/Tonsillitis: Safety and effectiveness in the treatment of pediatric patients with pharyngitis /tonsillitis under 2 years of age have not been established.

DRUG INTERACTION:

Antacids: In patients receiving Azithromycin and Antacid, Azithromycin should be taken at least 1 hour before or 2 hours after antacid. *Cyclosporin & Digoxin:* Macrolides interfere with the metabolism of cyclosporin & digoxin. So caution should be exercised before coadministration of these drugs. *Ergot derivatives:* Because of the theoretical possibility of ergotism, Azithromycin and ergot derivatives should not be coadministered.

OVERDOSE:

There are 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.

Terfenadine: As with other macrolides, azithromycin should be administered with caution in combination with terfenadine. There have been no pharmacokinetic drug interactions between Azithromycin and Warfarin, Theophylline, Carbamazepine, Methylprednisolone and Cimetidine.

STORAGE:

Store in a dry and cool place, below 30^o C temperature and keep away from light and moisture. Keep out of the reach of children.

PACKING:

Telide[®] 500 Tablet: Each box contains 2x7's tablets in Alu-Alu blister pack.

Telide[®] Powder for Suspension: Each bottle contains dry powder for reconstitution of 15 ml, 35 ml & 50 ml suspension with a 1.25 ml, 2.50 ml dropper and a 10 ml measuring cup.



Manufactured by

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