

ABACTEN

Azithromycin USP



Presentation

Abacten 500 tablet : Each tablet contains Azithromycin Dihydrate USP equivalent to Azithromycin 500 mg.

Abacten dry powder for suspension : When reconstituted, each 5 ml suspension contains Azithromycin 200 mg as Azithromycin Dihydrate USP.

Properties

Azithromycin is an azalide, a sub-class macrolide antibiotics. Azithromycin demonstrates activity in vitro, against a wide range of Gram-positive and Gram-negative bacteria including : Staphylococcus aureus, Streptococcus agalactiae, Streptococcus pneumoniae, Streptococcus pyogenes (Group A) and other Streptococcal species; Haemophilus influenzae, parainfluenzae; Moraxella catarrhalis; anaerobes pertussis; Bordetella parapertussis; Neisseria gonorrhoeae and Chlamydia trachomatis. Azithromycin also demonstrates in vitro activity against Mycoplasma pneumoniae; Campylobacter spp., and Treponema pallidum.

Pharmacokinetics

After oral administration, Azithromycin is widely distributed throughout the body; bioavailability is approximately 37%. The time taken to reach peak plasma level is 2-3 hours. Plasma terminal elimination half-life closely reflects the tissue depletion half-life of 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) indicating that the drug is highly tissue bound. Concentrations in target tissues such as lung, tonsil and prostate exceed the MIC 90 for likely pathogens after a single dose of 500mg.

Indication, Dosage & Administration

Infection	Recommended Dose	Duration of Therapy
Upper Respiratory tract infections: <i>Pharyngitis</i> <i>Tonsillitis</i> <i>Acute bacterial sinusitis</i> <i>Acute otitis media</i>	Adult : 500 mg once daily (or 500 mg once on day 1 followed by 250 once daily for next 4 days) Child : 10 mg/kg once daily	3 days
Lower Respiratory tract infections: <i>Community-acquired pneumonia</i> <i>Acute bacterial exacerbations of chronic obstructive pulmonary disease (COPD)</i> <i>Bronchitis</i>		
Acne	500 mg once daily for 3 days then 4 days interval	12 weeks (more effective)
Skin/ Skin structure infection	Adult : 500 mg once daily Child : 10 mg/kg once daily	3 days
Genital ulcer disease (chancroid)	Adult : 1 gram single dose	-
Non-gonococcal urethritis and cervicitis	Adult : 1 gram single dose	-
Gonococcal urethritis and cervicitis	Adult : 2 gram single dose	-
Typhoid/ Paratyphoid	Adult : 1 gram once daily Child : 20 mg/kg once daily	5 days
Diarrhoea	Adult : 1-1.5 gram once daily Child : 20 mg/kg once daily	-
Cholera	Adult : 1 gram single dose Child : 20 mg/kg single dose	-
Shigellosis	Adult : 1-1.5 gram once daily Child : 20 mg/kg once daily	1-5 days
Dental infection	Adult : 500 mg once daily Child : 10 mg/kg once daily	3 days
Eye infection (trachoma)	Adult : 1 gram single dose Child : 20 mg/kg single dose	-

Elderly : Same as for adult

Side-effects

Azithromycin is well tolerated with a low incidence of side-effects. The side-effects include nausea, vomiting, abdominal discomfort (pain/cramps), flatulence, diarrhoea, headache, dizziness, and skin rashes are reversible upon discontinuation of therapy. Reversible elevations in liver transaminases have been observed occasionally.

Contraindications

Azithromycin is contraindicated in patients with a known hypersensitivity to Azithromycin or any of the macrolide antibiotics. Because of the theoretical possibility of ergotism, Azithromycin and Ergot derivatives should not be co-administered. As with erythromycin and other macrolides, rare serious allergic reactions, including angioneurotic edema and anaphylaxis, have resulted in recurrent symptoms and required a long period of observation and treatment.

Use in pregnancy & lactation

Pregnancy : US FDA pregnancy category B. In the animal studies, no evidence of harm to the fetus due to Azithromycin was found. Because animal reproduction studies are not always predictive of human response, Azithromycin should be used during pregnancy only if clearly needed.

Lactation : It is not known whether Azithromycin is excreted in human milk. Caution should be exercised when Azithromycin is administered to nursing mother.

Precautions and Warning

As with any antibiotic, observation for signs of superinfection with non susceptible organism, including fungi is recommended.

Use in renal impairment

No dose adjustment is needed in patients with mild renal impairment (creatinine > 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 Azithromycin in these patients.

Drug Interactions

Peak serum levels but not the total extent of absorption were reduced by the presence of magnesium and aluminium containing antacids. Azithromycin should be taken at least 1hr before or 2hr after these antacids. Macrolides have been known to increase the plasma concentration of digoxin & cyclosporine. Therefore, if co-administration is necessary caution should be exercised and serum levels of digoxin & cyclosporine should be checked.

Direction for reconstitution

Shake the bottle to loosen the powder. Then add 25 ml purified or boiled and cooled water with the help of supplied measuring cup. Shake vigorously until the powder is well suspended.

Storage

Protect from light, store in dry place below 30°C.
Store the reconstituted suspension at room temperature and use within 5 days. Discard any unused medicine after 5 days. Keep out of reach of children.

Packs

Abacten 500 mg tablet: Each box contains 6 tablets (2 x 3's) in Alu-Alu blister pack.

Abacten 30 ml dry powder for suspension : Bottle containing dry powder for 30 ml suspension.



Manufactured by:
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