Azitar-500

Azithromycin Tablets U.S.P.

Composition:
Each film coated tablet contains:
Azithromycin dihydrate USP
Eq. To azithromycin anhydrous 500mg.

Introduction:
Azithromycin is an azalide antibiotic derived by the incorporation of a methyl-substituted nitrogen atom into the lactone ring of the macrolide nucleus. This substitution imparts more favorable pharmacodynamic and pharmacokinetic properties to the drug, namely a wide antibacterial spectrum, greater tissue penetration and longer elimination half-life.

Pharmacological Action:
The basic mechanism of action of azithromycin is inhibition of protein synthesis in the bacterial cell. Azithromycin binds reversibly to the 50S ribosomal subunit. This inhibits translocation of aminoacyl transfer – RNA and consequent protein synthesis.

Pharmacokinetics:
Following oral administration, Azithromycin is rapidly absorbed and widely distributed throughout the body. Rapid distribution into tissue and high concentration within cells result in significantly higher Azithromycin concentrations in tissues than in plasma or serum.
The serum protein binding of azithromycin is variable, decreasing from 51% at 0.02?g/ml to 7% at 2?g/ml. Biliary excretion of azithromycin, predominantly as unchanged drug, is a major route of elimination.

Indications:
Treatment of infections caused by sensitive organisms.
Lower Respiratory Tract Infections: Community – acquired pneumonias, acute bacterial exacerbations of chronic obstructive pulmonary disease, acute bronchitis due to Haemophilus influenzae, Moraxella catarrhalis or Streptococcus pneumoniae.
Upper Respiratory Tract Infections: Ear, nose and throat infections, e.g. tonsillitis, sinusitis, otitis media and pharyngitis.
Skin / Skin Structure Infections: Furunculosis, pyoderma and impetigo due to Staphylococcus aureus, S. pyogenes or S. agalactiae.
Sexually Transmitted Disease: Due to N. gonorrhoae and C. trachomatis.

Dosage and Directions for use:
Mild to moderate Bacterial Exacerbations of Chronic Obstructive Pulmonary Disease, Pneumonia, Pharyngitis / Tonsilitis and Uncomplicated Skin and Skin Structure Infections (>15 years of age): 500mg as a single dose on the 1st day followed by 250mg once daily on days 2 through 5 for a total dose of 1.5g or 500 mg once daily for 3 days.
Sexually Transmitted Diseases including Urethritis & Cervicitis due to C. trachomatis and N. Gonorrhoeae:
Single dose of 1 g.
Administer at least 1 hr before or 2 hrs after a meal. Azithromycin should not be taken with food.

Contra-Indications:
Hypersensitivity to erythromycin or any macrolide antibiotic.

Warnings:
Hepatic/Renal function impairment: Because azithromycin is principally eliminated via the liver, caution should be exercised when administered to patients with impaired hepatic function. There is no date regarding azithromycin usage in patients with renal impairment, however, caution should be exercised when prescribing azithromycin to these patients.

Use in lactation: It is not known whether azithromycin is excreted in breast milk. Exercise caution when administering to a nursing woman.
Use in the elderly: Pharmacokinetic parameters in older volunteers (65-85 years) were similar to those in younger volunteers (18-40 years) for the 5day therapeutic regimen. Dosage adjustment does not appear to be necessary for older patients with normal renal and hepatic function receiving treatment with this dosage regimen.

Side Effects and Special Precautions:
Most adverse effects are mild to moderate in severity and are reversible upon discontinuation of azithromycin. Overall, the most common adverse effect in patients receiving the multiple – dose regimen was related to the gastrointestinal system with diarrhoea (5), nausea and abdominal pain (3%) being the most frequently reported.
The following adverse reaction occurred in <1% of patients:
Cardiovascular: Palpitations and chest pain.
Gastrointestinal: Dyspepsia, flatulence, vomiting, melena and cholestatic jaundice.
Genitourinary: Monilasis, vaginitis and nephritis.
Central Nervous System: Dizziness, vertigo, somnolence and fatigue.
Allergic: Rash, photosensitivity and angioedema.

Drug Interactions:
Aluminium and magnesium containing antacids reduce the peak serum levels but not the extent of azithromycin absorption. Therefore, patients should be cautioned not to take the aluminium and magnesium containing antacids and azithromycin simultaneously.
Theophylline: Azithromycin did not affect the plasma levels or pharmacokinetics of theophyllline administered as a single IV dose. However, concurrent use of macrolides and theophylline has been associated with increases in serum concentrations of theophylline.
Therefore, until further data is available, plasma theophylline levels must be carefully monitored in patients receiving azithromycin concomitantly.
Warfarin: Azithromycin does not affect the prothrombin time response to a single dose of warfarin. However, concurred use of macrolides and warfarin has been associated with increased anticoagulant effects.
Prothrombin time should be carefully monitored in all patients being treated with azithromycin and warfarin concomitantly.
Known symptoms of over dosage and particulars of its Treatment:
Potentially serious of life–threatening reactions have not been reported. Allergic reactions have been uncommon With azithromycin. Gastrointestinal side effects should be treated symptomatically.

Storage instructions:
Store below 30°C, Protect from sunlight.
Keep out of reach of children.

Presentation:
Tablets are available in Alu-Alu of 10 x 1 x 3 Tablets

Manufactured in India by:
MAXTAR BIO-GENICS
K-No. 705, Nalagarh Road, Malku
Majra, Baddi-173205 (H.P.)