AZITHROMYCIN

Rx SITIMAX-200

200 mg/5 mL

Powder for Oral Suspension

Antibacterials

FORMULATION:

Each 5ml suspension contains:

Azithromycin U.S.P .....200mg. (as dihydrate)

PHARMACOKINETICS:

Following oral administration about 40% of a dose of Azithromycin is bio-available. Absorption from the capsule formulation, but not the tablet formulation, is reduced by food. Peak plasma concentrations are achieved 2 to 3 hours after a dose, but Azithromycin is extensively distributed to the tissues, and tissue concentrations subsequently remain much higher than those in the blood; in contrast to most other antibacterial, plasma concentrations are therefore of little value as a guide to efficacy. High concentrations are taken up into white blood cells. There is little diffusion into the CSF when meninges are not inflamed. Small amounts of Azithromycin are demethylated in the liver, and it is excreted in bile as unchanged drug and metabolites. About 6% of an oral dose (representing about 20% of the amount in the systemic circulation) is excreted in the urine. The terminal elimination half-life is probably in excess of 40 hours.

INDICATIONS:

Azithromycin is indicated for the treatment of patients with mild to moderate infections caused by susceptible strains of the designated microorganisms in the specific conditions listed below.

Acute bacterial exacerbation of chronic obstructive pulmonary disease due to Haemophilus influenzae, Moraxella catarrhalis, or Streptococcus pneumoniae.

Community-acquired pneumonia due to Chlamydia pneumoniae, Haemophilus influenzae, Mycoplasama pneumoniae, or Streptococcus pneumoniae in patients appropriate for oral therapy.

Pharyngitis/tonsillitis caused by Streptococcus pyogenes as an alternative to first-line therapy in individuals who cannot use first-line therapy.

Urethritis and cervicitis due to Chlamydia trachomatis or Neisseria gonorrhoeae. Genital ulcer disease in men due to Haemophilus ducreyi (chancroid). Due to the small number of women included in clinical trials, the efficacy of Azithromycin in the treatment of chancroid in women has not been established.

Acute otitis media caused by Haemophilus influenzae, Moraxella catarrhalis, or Streptococcus pneumoniae. Community-acquired pneumonia due to Chlamydia pneumoniae, Haemophilus influenzae, Mycoplasama pneumoniae, or Streptococcus pneumoniae in patients appropriate for oral therapy.

DOSAGE AND ADMINISTRATION:

ADULTS

The recommended dose of Azithromycin for the treatment of mild to moderate acute bacterial exacerbation of chronic obstructive pulmonary disease, community-acquired pneumonia of mild severity, pharyngitis/tonsillitis (as second-line therapy), and uncomplicated skin and skin structure infections due to the indicated organisms is: 500 mg as a single dose on the first day followed by 250 mg once daily on days 2 through 5.

The recommended dose of Azithromycin for the treatment of genital ulcer disease due to Haemophilus ducreyi (chancroid), non-gonococcal urethritis and cervicitis due to C. trachomatis is a single 1gm dose per day.

The recommended dose of Azithromycin for the treatment of urethritis and cervicitis due to Neisseria gonorrhoeae is a single 2gm dose of Azithromycin.

CHILDREN

The recommended dose of Azithromycin for the treatment of children with acute otitis media and community-acquired pneumonia is 10 mg/kg as a single dose on the first day (not to exceed 500 mg/day) followed by 5 mg/kg on days 2 through 5 (not to exceed 250 mg/day).

The recommended dose for children with pharyngitis/tonsillitis is 12 mg/kg once a day for 5 days (not to exceed 500 mg/day).

PEDIATRIC PATIENTS:

Azithromycin is not recommended in pediatric patients of less than 6 months of age. Whereas for children from 6 months to 4 years for acute otitis media and community acquired pneumonia is 5mg/kg/day; for pharyngitis/tonsillitis the recommended dose is 6mg/kg/day of the body weight.

CONTRA INDICATIONS:

Azithromycin is contraindicated in patients with known hypersensitivity to Azithromycin, erythromycin, or any macrolide antibiotic. Contraindicated in pregnant women and lactating mothers.

PRECAUTIONS:
Because Azithromycin is principally eliminated via the liver, caution should be exercised when Azithromycin is administered to patients with impaired hepatic function. There are no data regarding Azithromycin usage in patients with renal impairment; thus, caution should be exercised when prescribing Azithromycin in these patients.
Patients should be cautioned to take Azithromycin orally at least one hour prior to a meal or at least two hours after a meal. These medications should not be taken with food. Azithromycin should be used during pregnancy only if clearly needed. It is not known whether Azithromycin is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Azithromycin is administered to a nursing woman.
REPORTING OF SUSPECTED ADVERSE REACTION: To allow continued monitoring of the benefit/risk balance of the medicinal product, reporting of suspected adverse reaction is necessary. Healthcare professionals are encouraged to report any suspected adverse reactions directly to the importer/distributor and/or report to FDA: www.fda.gov.ph. Patients are advised to seek immediate medical attention at first sign/s of adverse reactions.
ADVERSE EFFECTS:
In clinical trials, most of the reported side effects were mild to moderate in severity and were reversible upon discontinuation of the drug. Approximately 0.7% of the patients (adults and children) from the multiple-dose clinical trials discontinued Azithromycin therapy because of treatment-related side effects. Most of the side effects leading to discontinuation were related to the gastrointestinal tract, e.g., nausea, vomiting, diarrhea, or abdominal pain. Potentially serious side effects of angioedema and cholestatic jaundice were reported rarely. Some other rarely seen adverse effects are as follows,
Cardiovascular :Palpitations, chest pain.
Gastrointestinal :Dyspepsia, flatulence, vomiting, melena, and cholestatic jaundice.
Genitourinary :Monilia, vaginitis, and nephritis.
Nervous system :Dizziness, headache, vertigo, and somnolence.
General :Fatigue.
Allergic :Rash, photosensitivity, and angioedema.
DRUG INTERACTION:
Aluminum- and magnesium-containing antacids reduce the peak serum levels (rate) but not the AUC (extent) of Azithromycin absorption. Administration of cimetidine (800 mg) two hours prior to Azithromycin had no effect on Azithromycin absorption.
Azithromycin did not affect the plasma levels or pharmacokinetics of theophylline administered as a single intravenous dose. The effect of Azithromycin on the plasma levels or pharmacokinetics of theophylline administered in multiple doses resulting in therapeutic steady-state levels of theophylline is not known. However, concurrent use of macrolides and theophylline has been associated with increases in the serum concentrations of theophylline. Therefore, until further data are available, prudent medical practice dictates careful monitoring of plasma theophylline levels in patients receiving Azithromycin and theophylline concomitantly.
Azithromycin did not affect the prothrombin time response to a single dose of warfarin. However, prudent medical practice dictates careful monitoring of prothrombin time in all patients treated with Azithromycin and warfarin concomitantly. Concurrent use of macrolides and warfarin in clinical practice has been associated with increased anticoagulant effects.
The following drug interactions have not been reported in clinical trials with Azithromycin; however, no specific drug interaction studies have been performed to evaluate potential drug-drug interaction. Nonetheless, they have been observed with macrolide products. Until further data are developed regarding drug interactions when Azithromycin and these drugs are used concomitantly, careful monitoring of patients is advised:
Digoxin: Elevated Digoxin levels.
Ergotamine or dihydroergotamine: Acute ergot toxicity characterized by severe peripheral vasospasm and dysesthesia.
Triazolam: It decreases the clearance of triazolam and thus may increase the pharmacologic effect of triazolam.
Drugs metabolized by the cytochrome P450 system: Elevations of serum carbamazepine, terfenadine, cyclosporine, hexobarbital, and phenytoin levels.
Laboratory Test Interactions: There are no reported laboratory test interactions.
INSTRUCTIONS: Discard the suspension after 7 days if stored at room temperature. And after 14 days if stored in refrigerator at temperatures 2-8°C.
CAUTIONS:
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.
AVAILABILITY:
USP type III amber glass bottle x 15 mL and 60 mL(Box of 1's)
FDA Registration Number: DR-XY42983
Date of Renewal of Authorization: 13 March 2019
Date of Revision of Package Insert: 22 March 2023

Manufactured by:
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