

For consumer information only

^{Rx} Azispeed[®]-500

(Azithromycin 500 mg Tablets)

Composition:

Each film coated tablet Contains:

Azithromycin Dihydrate I.P.....500 mg

Excipients... q.s.

Clinical Pharmacology:

Azithromycin is a Macrolides class of antibiotic which inhibits protein synthesis of bacterial cell. It impairs the elongation cycle of the peptidyl chain by specifically binding to the 50 S subunit of the ribosome.

Indications:

- Upper Respiratory Tract Infections.
- Lower Respiratory Tract Infections.
- Skin & Soft Tissue Infections.
- Community Acquired Pneumonia.
- Urogenital infections.
- Sexually Transmitted Diseases.

Use in special population:

Lactation:

Azithromycin has been reported to be excreted in human breast milk in small amounts. Caution should be exercised when azithromycin is administered to a nursing woman.

Contraindications:

Patients with known hypersensitivity to azithromycin, erythromycin, any macrolide or ketolide drug.

Patients with a history of cholestatic jaundice/hepatic dysfunction associated with prior use of azithromycin.

Precautions and Warnings:

- Hepatotoxicity: Severe, and sometimes fatal, hepatotoxicity has been reported; discontinue the medication immediately if signs and symptoms of hepatitis occur.
- Medicines known as ergot derivatives e.g. ergotamine or dihydroergotamine (medicines used for migraines or reducing blood flow) should not be taken together with azithromycin
- Care must be taken if you suffer from severe heart problems.
- Care must be also taken if you suffer from neurological or psychiatric diseases.

Drug Interactions:

- Amiodarone: Increased risk of cardiotoxicity (QTc prolongation)
- Cyclosporine: Concomitant administration may increase cyclosporine levels. Close Monitoring of cyclosporine levels is recommended
- Nelfinavir: Coadministration may lead to increased azithromycin levels
- Phenytoin: Concomitant administration may increase phenytoin levels. Close monitoring of phenytoin levels is recommended

Adverse effects:

Abdominal cramps, nausea, diarrhea, anorexia, pancreatitis, renal failure, headache, fatigue, itching.

Overdosage:

Overdose may lead to severe nausea, vomiting and diarrhoea and reversible loss of hearing.

Route of administration: Oral.

Type of tablet: Film coated tablet.

Dosage:

As Directed by the Physician.

Storage

Store in cool, dry & dark place.

SCHEDULE H PRESCRIPTION DRUG-CAUTION: Not to be sold retail without the prescription of a Registered Medical Practitioner.

Presentation: Azispeed-500 tablet available as 1x 5 tablet strip.

Marketed By:



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