Zetron®

Azithromycin Capsules and Dry Suspension

Composition:

Capsules: Each capsule contains Azithromycin 250mg.
Excipients: Lactose, starch, sodium lauryl sulphate and magnesium stearate.

Dry Suspension:
15 ml: Each reconstituted 5ml contains: Azithromycin 200mg.
22.5ml: Each reconstituted 7.5ml contains: Azithromycin 300mg.
Excipients: Sucrose, tribasic sodium phosphate, xanthan gum, hydroxypropyl cellulose, and banana flavor.

Properties:

Azithromycin is an azalide, a subclass of macrolide antibiotics. Azithromycin differs from other antibiotics as its high tissue affinity. It interferes with microbial protein synthesis by binding to the 50s ribosomal subunit of susceptible microorganisms. It is rapidly absorbed and widely distributed throughout the body following oral administration.
The tissue concentrations exceed those in plasma up to 50 times and the tissue half lives range between 2 and 4 days. Therefore, the dosage regimen for **Zetron** differs than that of antimicrobials. The serum protein binding of azithromycin is variable in concentration. The major route of elimination is the biliary excretion as unchanged drug.

Indications:

Zetron clinically indicated in particular in infections caused by Azithromycin susceptible pathogens such as:
- Infections of the upper respiratory tract including sinusitis, pharyngitis, tonsillitis.
- Otitis media.
- Infections of the lower respiratory tract including bronchitis and pneumonia.
- Infections of skin and soft tissues.
- Uncomplicated genital infections caused by chlamydia tracomatis or neisseria gonorrhoea (non-multi-resistant strains): concurrent use in trepenoma pallidium should be excluded.

Contraindications:

Zetron is contraindicated for patients with known hypersensitivity to any of its components or to erythromycin or any macrolide antibiotic.
It is contraindicated to use pimozide concurrently with azithromycin.

Precautions:

Caution should be taken when the drug is administered to patients with impaired hepatic or renal function, and to nursing mothers.

Interactions with other drugs:

Concomitant use of :
- Aluminum and magnesium containing antacids reduce the peak plasma level of azithromycin.
- Neither pharmacokinetic nor clinical studies have revealed any evidence of interactions with theophylline.
  Since interactions between theophylline and some macrolides have been described, patients should monitored regarding typical reactions of increased theophylline levels when azithromycin and theophyllines are co-administered.
- Azithromycin/Miscellaneous with other drugs: Macrolides antibiotics are known to interact with trizolam, cyclosporin and digoxin. For azithromycin, sufficient data are not available but the possibility of interactions should be born in mind.

In studies with healthy subjects, co-administration of azithromycin did not affect carbamazipine serum levels significantly and its active metabolite was not also influenced. Likewise, there was no significant mutual influence for methyl-prednisolone.
Concurrent use of warfarin with macrolide antibiotics has been associated with increased anti-coagulant effects, prothrobin time should be monitored carefully in patients concurrently receiving azithromycin and warfarin.
Some broad-spectrum antibiotics may reduce the efficacy of combined oral contraceptives.

Warnings:

Discontinue the use of azithromycin if any signs of allergic reactions occurred.
Azithromycin should not be used in patients with pneumonia and have any of the following risk factors:
Cystic fibrosis, nosocomially acquired infections, bacteremia, patients requiring hospitalization and elderly patients.
As with other antibacterial agents, Pseudomembranous colitis may occur, therefore, it is important to consider this diagnosis in patients who present with diarrhea following administration of azithromycin.

Dosage and Administration:

Adults:
The recommended dose is 500mg as a single dose on the first day followed by 250mg once daily for 5 days.
Zetron capsules should be given at least 1 hour before or 2 hours after a meal, and should not be taken with food.

Children:
The recommended dose is 10mg/kg as a single dose on the first day followed by 5mg/kg for 5 days.
Zetron oral suspension should be given at least 1 hour before or 2 hours after a meal, and should not be taken with food.

Overdosage:

Symptoms of overdosage may include nausea, vomiting and diarrhea.

Side Effects:

Most of the side effects include nausea, vomiting, diarrhea, abdominal pain, palpitations, chest pain, flatulence, dyspepsia, dizziness, headache, vertigo, fatigue, rash and photosensitivity.
Consult your Pharmacist or Physician if any side effect is observed.

Pharmaceutical Precautions:

Keep at room temperature (15-30 °C).
Do not use beyond the expiry date or if the product shows any signs of deterioration.

Reconstitution:

Zetron 15 ml: Tab bottle to release powder. Add 9 ml water and shake well.
Zetron 22.5 ml: Tap bottle to release powder. Add 12 ml water and shake well.
The reconstituted solution should be used within 5 days.

Presentation:

Zetron Capsules : Pack of 6 Capsules.
Zetron OS 200mg/5ml : Bottle of 15ml.
Zetron OS 300mg/7.5ml : Bottle of 22.5ml.
Hospital packs are available.

THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Strictly follow the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children.

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