Important: Read carefully

Azi-once™

azithromycin

Oral Suspension

Composition:
Reconstituted suspension contains 200 mg of azithromycin base per 5ml.
Excipient(s): Xanthan gum, trisodium phosphate anhydrous, hydroxypropyl cellulose, banana flavour, fantasy flavour permaseal, fresh co frote flavour permaseal, collidal silicon dioxide, sucrose, purified water.

Therapeutic Category: Antibiotic, macrolide
Use: Treatment of acute otitis media due to H. *influenzae,* M. *catarrhalis,* or S. *pneumoniae;* pharyngitis/tonsillitis due to S. *pyogenes;* treatment of mild to moderate upper and lower respiratory tract infections, infections of the skin and skin structure, community-acquired pneumonia, pharyngitis/tonsillitis (alternative to first-line therapy), and genital ulcer disease (chancroid) due to susceptible strains of C. *trachomatis,* M. *catarrhalis, H. influenzae,* S. *aureus,* S. *pneumoniae, Mycoplasma pneumoniae,* and C. *psittaci;* acute bacterial exacerbations of chronic obstructive pulmonary disease (COPD) due to H. *influenzae,* M. *catarrhalis,* or S. *pneumoniae.*

Unlabeled/Investigational Use: Prevention of (or to delay onset of) or treatment of MAC in patients with advanced HIV infection; prophylaxis of bacterial endocarditis in patients who are allergic to penicillin and undergoing surgical or dental procedures.

Pregnancy: (Risk Factor B)
Pregnancy Implications: Azithromycin has been shown to cross the placenta. It has been used as an alternative treatment of *Chlamydia* in late-term pregnancy. There are no adequate and well-controlled studies in pregnant women; use during pregnancy only if clearly needed.
Lactation Enters breast milk/use with caution.

Contraindications: Hypersensitivity to azithromycin, other macrolide antibiotics, or any component of the formulation.

Warnings/Precautions: Use with caution in patients with hepatic dysfunction; hepatic impairment with or without jaundice has occurred chiefly in older children and adults; it may be accompanied by malaise, nausea, vomiting, abdominal colic, and fever; discontinue use if these occur; may mask or delay symptoms of incubating gonorrhea or syphilis, so appropriate culture and susceptibility tests should be performed prior to initiating azithromycin; pseudomembranous colitis has been reported with use of macrolide antibiotics; use caution with renal dysfunction; safety and efficacy have not been established in children <6 months of age with acute otitis media or community-acquired pneumonia, or in children <2 years of age with pharyngitis/tonsillitis.

Adverse Reactions:
1% to 10%: Gastrointestinal: Diarrhea, nausea, abdominal pain, cramping, vomiting (especially with high single-dose regimens).
<1% (Limited to important or life-threatening): Acute renal failure, allergic reaction, aggressive behavior, anaphylaxis, angioedema, arrhythmias (including ventricular tachycardia), cholestatic jaundice, deafness, enteritis, erythema multiform (rare), headache (especially with high-dose), hearing loss, hepatic necrosis (rare), hepatitis, hypertrophic pyloric stenosis, hypotension, interstitial nephritis, leukopenia, pancreatitis, paresthesia, pruritus, pseudomembranous colitis, seizures, somnolence. Stevens-Johnson syndrome (rare) syncope, taste abnormality, thrombocytopenia, tinnitus, tongue discoloration (rare), torsade de pointes, urticaria, vertigo.

Over dosage/Toxicology: Symptoms include nausea, vomiting, diarrhea, and prostration.
Treatment is supportive and symptomatic.

Drug Interactions:
Cytochrome P450 Effect: Substrate of CYP3A4 (minor); **Inhibits** CYP3A4 (weak).

Increased Effect/Toxicity: Concurrent use of pimozide is contraindicated due to potential cardiotoxicity. Azithromycin potentially may increase levels of tacrolimus, phenytoin, ergot alkaloids, alfentanil, astemizole, bromocriptine, carbamazepine, cyclosporine, digoxin, disopyramide, and triazolam. However, azithromycin did not affect the response/levels of carbamazepine, terfenadine, theophylline or warfarin in specific interaction studies; caution is advised when administered together. Nelfinavir may increase azithromycin serum levels (monitor for adverse effects).
Decreased Effect: Decreased azithromycin peak serum concentrations with aluminum and magnesium-containing antacids (by 24%), however, total absorption is unaffected.
Ethanol/Nutrition/Herb Interactions Food: Rate and extent of GI absorption may be altered depending upon the formulation. Azithromycin suspension has significantly increased absorption (46%) with food.

Mechanism of Action: Inhibits RNA-dependent protein synthesis at the chain elongation step; binds to the 50S ribosomal subunit resulting in blockage of transpeptidation.

Pharmacodynamics / Kinetics:
Absorption: Rapid
Distribution: Extensive tissue; distributes well into skin, lungs, sputum, tonsils, and cervix; penetration into CSF is poor
Metabolism: Hepatic
Bioavailability: 37%
Half-life elimination: Terminal: 68 hours
Time to peak, serum: 2.3-4 hours
Excretion: Feces (50% as unchanged drug); urine (~5% to 12%)

Dosage:
Children > 6 months:
Community-acquired pneumonia: 10 mg/kg on day 1 (maximum: 500 mg/day) followed by 5 mg/kg/day once daily on days 2-5 (maximum: 250 mg/day)
Otitis media:
1-day regimen: 30 mg/kg as a single dose (maximum dose: 1500 mg)
3-days regimen: 10 mg/kg once daily for 3 days (maximum: 500 mg/day)
5-days regimen: 10 mg/kg on day 1 (maximum: 500 mg/day) followed by 5 mg/kg/day once daily on days 2-5 (maximum: 250 mg/day)
Children > 2 years: Pharyngitis, tonsillitis: 12 mg/kg/day once daily for 5 days (maximum: 500 mg/day)

Prophylaxis for bacterial endocarditis (unlabeled use): 15 mg/kg 1 hour before procedure.

Dosage adjustment in renal impairment: Use caution in patients with Cl_{cr} <10 ml/minute

Pack Size:
Oral Suspension 200 mg/5 mL when reconstituted.
Available in three sizes : Powder for 15 mL, powder for 22.5 mL, powder for 30 ml.

Storage:
Suspension: Store dry powder below 25°C; following reconstitution, store suspension at 15°C to 25°C.

Instructions For Use:
Shake the bottle containing powder before adding water.
Add the water provided in the pack.
Before using the suspension, always shake the bottle well.
Discard after 5 days of reconstitution.

THIS IS A MEDICAMENT

- Medicament is a product that affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly 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.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of the reach of children.

Council of Arab Health Ministers & Union of Arab Pharmacists

General Medicine

Azi-once™ **is a quality product manufactured by:**

جمجوم فارما
Jamjoom Pharma

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