

Zitromac

Capsules and Tablets - Powder for oral suspension



Warning and Precautions:

- Hypersensitivity:** If an allergic reaction occurs, the drug should be discontinued and appropriate therapy should be instituted. Physicians should be aware that reappearance of the allergic symptoms may occur when symptomatic therapy is discontinued.
- Hepatotoxicity:** Abnormal liver function, hepatitis, cholestatic jaundice, hepatic necrosis, and hepatic failure have been reported, some of which have resulted in death. Discontinue azithromycin immediately if signs and symptoms of hepatitis occur.
- Diarrhea:** Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including Azithromycin - Medico, and may range in severity from mild diarrhea to fatal colitis.
- Due to the limited data in subjects with GFR <10 mL/min, caution should be exercised when prescribing azithromycin in these patients.
- Prolonged cardiac repolarization and QT interval, imparting a risk of developing cardiac arrhythmia and torsades de pointes, have been seen in treatment with other macrolides. A similar effect with azithromycin cannot be completely ruled out in patients at increased risk for prolonged cardiac repolarization.
- Myasthenia gravis: Exacerbations of the symptoms of myasthenia gravis and new onset of myasthenia syndrome have been reported in patients receiving azithromycin therapy.

Pregnancy and Lactation:

Pregnancy: Pregnancy Category " B " There are, however, no adequate and well-controlled studies in pregnant women. Azithromycin should be used during pregnancy only if clearly needed.
Lactation: Azithromycin has been reported to be secreted into human breast milk, but there are no adequate and well-controlled clinical studies in breastfeeding women that have characterized the pharmacokinetics of azithromycin excretion into human breast milk.

Drug Interactions:

- Antacids:** In patients receiving both azithromycin and antacids, the drugs should not be taken simultaneously.
- Ergot derivatives:** Because of the potential for ergotism, the concomitant use of azithromycin and ergot derivatives is not recommended.
- Due to its hepatic metabolism, caution should be exercised when administering this agent with other drugs metabolized in the liver.
- The following drug interactions are clinically relevant but do not represent the comprehensive list of documented or potential drug-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.

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.

Side Effects: In clinical trials, most of the reported side effects were mild to moderate in severity and were reversible upon discontinuation of the drug. The following side effects may appear:

Gastrointestinal: abdominal cramps, nausea, diarrhea, anorexia, pancreatitis

Genitourinary: vulvovaginal candidiasis

Cardiovascular System: prolongation of QT interval

Hepatic: hepatotoxicity, jaundice

Hematologic: eosinophilia, thrombocytosis, lymphopenia

Central Nervous System: headache, fatigue

Endocrine/Metabolic: hyperglycemia

Dermatologic: itching, nail discoloration

If you get any of the side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

Dosage & Administration: Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The capsules or Tablets should be swallowed whole.

Adults and children with a body weight of 45 kg and above:

*Infection	Recommended Dose/Duration of Therapy
Community-acquired pneumonia Pharyngitis/tonsillitis (second-line therapy) Skin/skin structure (uncomplicated)	500 mg as a single dose on Day 1, followed by 250 mg once daily on Days 2 through 5
Acute bacterial exacerbations of chronic obstructive pulmonary disease	500 mg once daily for 3 days OR 500 mg as a single dose on Day 1, followed by 250 mg once daily on Days 2 through 5
Acute bacterial sinusitis	500 mg once daily for 3 days
Genital ulcer disease (chancroid)	One single 1-gram dose
Non-gonococcal urethritis and cervicitis	One single 1-gram dose
Gonococcal urethritis and cervicitis	One single 2-gram dose

*Due to the indicated organism

Dosing in pediatrics:

Zitromac for oral suspension can be taken with or without food. The dose is calculated according to the following table (In children 6 months or older):

Weight (Kg)	OTITIS MEDIA AND ACUTE BACTERIAL SINUSITIS: (3-Day Regimen)	OTITIS MEDIA AND COMMUNITY-ACQUIRED PNEUMONIA (5-Day Regimen)		Otitis media, acute (1-Day Regimen)
	Day 1- 3 10 mg/kg/day	Day 1 10 mg/kg/day	Day 2 - 5 5mg/kg/day	30mg/kg As a single dose
5	1.25 ml	1.25 ml	0.625 ml	3.75 ml
10	2.5 ml	2.5 ml	1.25 ml	7.5 ml
20	5 ml	5 ml	2.5 ml	15 ml
30	7.5 ml	7.5 ml	3.75 ml	22.5 ml
40	10 ml	10 ml	5 ml	30 ml
50 and above	12.5 ml	12.5 ml	6.25 ml	37.5 ml

Age 2 years and above:

Weight (Kg)	Pharyngitis/tonsillitis (5 days regimen) 12 mg/kg/day
8	2.5 ml
17	5 ml
25	10 ml
40	12.5 ml

Preparation of the suspension:

- Shake the dry powder loose.
- Add the amount of water described below to the powder.
For 15 ml (600 mg) reconstituted suspension: add 12 ml water.
For 30 ml (1200 mg) reconstituted suspension: add 24 ml water.
- Shake the package well.

Overdose: The undesirable effects at doses in excess of those recommended were similar to those after normal doses. The typical symptoms of an overdose with macrolide antibiotics include reversible loss of hearing, severe nausea, vomiting and diarrhoea. In cases of overdose, administration of medicinal charcoal and general symptomatic treatment as well as measures to support vital functions are indicated where necessary.

Storage: Keep this medicine out of the sight and reach of children.

Store below 25°C. Store in the original package.

Packaging:

capsules and Tablets: Each Zitromac 250 carton box contains 6 capsules or 6 film coated tablets.

Each Zitromac 500 carton box contains 3 capsules or 3 film coated tablets.

Powder for oral suspension:

Carton box contains plastic bottle for preparation oral suspension 15 ml of

Azithromycin 200 mg / 5 ml.

Carton box contains plastic bottle for preparation oral suspension 30 ml of

Azithromycin 200 mg / 5 ml.

"A medication is a product which affects your health, and it's consumption contrary to instructions is dangerous for you."
 - Follow strictly the doctors prescription, the method of use and the instructions of the pharmacist who sold the medication.
 - The doctor and the pharmacist experts in medicine, its benefits and risks.
 - Do not repeat the same prescription without consulting your doctor.
 - KEEP THE MEDICAMENTS OUT OF REACH OF CHILDREN
 Council of Arab Health Ministers, Union of Arab Pharmacists

Revapharmaceutical Industry - Syria

Composition:

Capsules and Tablets:

Each Capsule or Film Coated Tablet (Zitromac 250) Contains: Azithromycin 250 mg.

Each Capsule or Film Coated Tablet (Zitromac 500) Contains: Azithromycin 500 mg.

Powder for oral suspension:

Each 5 ml of Zitromac Oral Suspension contains: Azithromycin 200 mg.

Mechanism of Action:

Azithromycin is a macrolide antibiotic. It acts by binding to the 23S rRNA of the 50S ribosomal subunit of susceptible microorganisms inhibiting bacterial protein synthesis.

Antimicrobial Spectrum:

Azithromycin is a broad-spectrum macrolide antibiotic with bacteriostatic activity against many Gram-positive and Gram-negative bacteria and against Other microorganisms such as Chlamydia trachomatis. Azithromycin can affect the following organisms:

Commonly susceptible species		
Aerobic Gram-positive microorganisms	Aerobic Gram-negative microorganisms	Anaerobic microorganisms
Staphylococcus aureus Methicillin-susceptible	Haemophilus influenzae Haemophilus parainfluenzae	Clostridium perfringens
Streptococcus pneumoniae Penicillin-susceptible	Legionella pneumophila	Fusobacterium spp.
Streptococcus pyogenes (Group A)	Moraxella catarrhalis	Prevotella spp.
	Pasteurella multocida	Porphyromonas spp.

Pharmacokinetics: Azithromycin is not affected by gastric acidity, so it can be taken orally as it is easily absorbed, but the amount of absorption is greater when taking the drug on an empty stomach. The time to reach peak concentration (Tmax) in adults is 2 to 3 hours after the oral dose. The concentration of azithromycin in tissues is higher than in plasma due to its high lipid solubility. The half-life of azithromycin allows for a single daily dose while maintaining adequate antimicrobial levels in affected tissues for several days.

Following a single dose of 500 mg, the apparent terminal elimination half-life of azithromycin is 68 hours.

Biliary excretion of azithromycin, predominantly unchanged, is a major route of elimination. Over the course of a week, about 6% of the administered dose appears as unchanged drug in urine.

Indications:

Zitromac (azithromycin) is a macrolide antibacterial drug 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.

Adult Patients:

- Acute bacterial exacerbations of chronic bronchitis due to Haemophilus influenzae, Moraxella catarrhalis, or Streptococcus pneumoniae.
- Acute bacterial sinusitis due to Haemophilus influenzae, Moraxella catarrhalis, or Streptococcus pneumoniae.
- Community-acquired pneumonia due to Chlamydophila pneumoniae, Haemophilus influenzae, Mycoplasma 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.
- Uncomplicated skin and skin structure infections due to Staphylococcus aureus, Streptococcus pyogenes, or Streptococcus agalactiae.
- Urethritis and cervicitis due to Chlamydia trachomatis or Neisseria gonorrhoeae.
- Genital ulcer disease due to Haemophilus ducreyi (chancroid).

Pediatric Patients:

- Acute otitis media (>6 months of age) caused by Haemophilus influenzae, Moraxella catarrhalis, or Streptococcus pneumoniae.
- Community-acquired pneumonia (>6 months of age) due to Chlamydophila pneumoniae, Haemophilus influenzae, Mycoplasma pneumoniae, or Streptococcus pneumoniae in patients appropriate for oral therapy.
- Pharyngitis/tonsillitis (>2 years of age) caused by Streptococcus pyogenes as an alternative to first-line therapy in individuals who cannot use first-line therapy.

Contraindications:

Azithromycin is contraindicated in patients with known hypersensitivity to azithromycin, erythromycin, any macrolide or ketolide antibiotic. Azithromycin is contraindicated in patients with a history of cholestatic jaundice/hepatic dysfunction associated with prior use of azithromycin.

