azithromycin (ay-zith-ro-mye-sin)

Classification
Therapeutic: agents for atypical mycobacterium, anti-infectives
Pharmacologic: macrolides

Pregnancy Category B

Indications
Treatment of the following infections due to susceptible organisms: Upper respiratory tract infections, including streptococcal pharyngitis, acute bacterial exacerbations of chronic bronchitis and sinusitis; Lower respiratory tract infections, including bronchitis and pneumonia; Acute otitis media; Skin and skin structure infections; Nongonococcal urethritis, cervicitis; gonorrhea; and chancroid. Prevention of disseminated Mycobacterium avium complex (MAC) infection in patients with advanced HIV infection. Extended-release suspension (ZMax): Acute bacterial sinusitis and community-acquired pneumonia in adults. Unlabeled Use: Prevention of bacterial endocarditis. Treatment of cystic fibrosis lung disease. Treatment and post-exposure prophylaxis of pertussis in infants.

Action
Inhibits protein synthesis at the level of the 50S bacterial ribosome.

Therapeutic Effects: Bacteriostatic action against susceptible bacteria.

Spectrum: Active against the following gram-positive aerobic bacteria: Staphylococcus aureus, Streptococcus pneumoniae, S. pyogenes (group A strep). Active against these gram-negative aerobic bacteria: Haemophilus influenzae, Moraxella catarrhalis, Neisseria gonorrhoeae. Also active against: Bordetella pertussis, Mycoplasma, Legionella, Chlamydia pneumoniae, Ureaplasma urealyticum, Borrelia burgdorferi, M. avium. Not active against methicillin-resistant S. aureus.

Pharmacokinetics
Absorption: Rapidly absorbed (40%) after oral administration. IV administration results in complete bioavailability.

Distribution: Widely distributed to body tissues and fluids. Intracellular and tissue levels exceed those in serum; low CSF levels.

Protein Binding: 7–51%.

Metabolism and Excretion: Mostly excreted unchanged in bile. 4.5% excreted unchanged in urine.

Half-life: 11–14 hr after single dose; 2–4 days after several doses; 59 hr after extended-release suspension.

TIME/ACTION PROFILE (serum)

<table>
<thead>
<tr>
<th>ROUTE</th>
<th>ONSET</th>
<th>PEAK</th>
<th>DURATION</th>
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<tbody>
<tr>
<td>IV</td>
<td>rapid</td>
<td>end of infusion</td>
<td>24 hr</td>
</tr>
<tr>
<td>PO</td>
<td>rapid</td>
<td>2.5–3.2 hr</td>
<td>24 hr</td>
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Contraindications/Precautions
Contraindicated in: Hypersensitivity to azithromycin, erythromycin, or other macrolide anti-infectives; History of cholestatic jaundice or hepatic dysfunction with prior use of azithromycin; QT interval prolongation, hypokalemia, hypomagnesemia, or bradycardia; Concurrent use of quinidine, procainamide, dofetilide, amiodarone, or sotalol.

Use Cautiously in: Severe liver impairment (dose adjustment may be required); Severe renal impairment (CrCl < 10 mL/min); Myasthenia gravis (may worsen symptoms); Geri: May have ↑ risk of QT interval prolongation; OB, Lactation: Safety not established.

Adverse Reactions/Side Effects
CNS: dizziness, seizures, drowsiness, fatigue, headache.

CV: TORSADES DE POINTES, chest pain, hypotension, palpitations, QT interval prolongation, hyperkalemia, hypomagnesemia, hyperphosphatemia, hyperuricemia.

GI: HEPATOTOXICITY, PSEUDOMEMBRANOUS COLITIS, abdominal pain, diarrhea, nausea, cholestatic jaundice, elevated liver enzymes, dyspepsia, flatulence, melena, oral candidiasis, pyloric stenosis.

GU: nephritis, vaginitis.

Hemat: anemia, leukopenia, thrombocytopenia.

Derm: STEVENS-JOHNSON SYNDROME, TOXIC EPIDERMAL NECROLYSIS, photosensitivity, rash, ERYTHEMA MULTIFORME, TENSYL PHENOMENON, erythema, urticaria, stomatitis, angular cheilitis, pruritus.

EENT: ototoxicity.

F and E: hyperkalemia.

Misc: ANGIOEDEMA.

Interactions
Drug-Drug: Quinidine, procainamide, digoxin, valproate, and amiodarone may ↑ risk of QT interval prolongation; concurrent use should be avoided. Alumino- and magnesium-containing antacids ↓ peak levels. Nelfinavir ↑ levels (monitor carefully); azithromycin also ↓ nelfinavir levels. Efavirenz ↓ levels. May ↓ the effects and risk of toxicity of warfarin and zidovudine. Other macrolide anti-infectives also ↓ warfarin levels.

Other: ↓ diuresis; ↑ serum levels of lithium.

Product Information
References

infectious have been known to q levels and effects of digoxin, theophylline, ergotamine, dihydroergotamine, triazolam, carbamazepine, tacrolimus, and phenytoin; careful monitoring of concurrent use is recommended.

Route/Dosage

Most Respiratory and Skin Infections

PO (Adults): 500 mg on 1st day, then 250 mg/day for 4 more days (total dose of 1.5 g). Acute bacterial sinusitis — 500 mg once daily for 3 days or single 2-g dose of extended-release suspension (Zmax).

PO (Children ≥ 6 mo): Pneumonia — 10 mg/kg on 1st day, then 5 mg/kg (not > 500 mg/dose) for 4 more days. Pharyngitis/tonsillitis — 12 mg/kg once daily for 5 days (not > 500 mg/dose). Acute bacterial sinusitis — 10 mg/kg/day for 3 days.

PO (Neonates): Pertussis, treatment and post-exposure prophylaxis — 10 mg/kg once daily for 5 days.

Otitis media

PO (Children ≥ 6 mo): 50 mg/kg single dose (not > 1500 mg/dose) or 20 mg/kg/day as a single dose (not > 1000 mg/dose) for 5 days or 10 mg/kg as a single dose (not > 500 mg/dose) on 1st day, then 5 mg/kg as a single dose (not > 250 mg/dose) daily for 4 more days.

Acute bacterial exacerbations of chronic bronchitis

PO (Adults): 250 mg for 4 more days (total dose of 1.5 g) or 500 mg/day for 3 days.

Community-Acquired Pneumonia

PO (Adults): 500 mg for 1 hr before procedure.

PO (Children): 15 mg/kg for 1 hr before procedure.

Nongonococcal Urethritis, Cervicitis, Chancroid, Chlamydia

PO (Adults): Single 1-g dose.

PO (Children): Gonorreal: Single 20-mg/kg dose (not > 1000 mg/dose). Zmax: Single 10-mg/kg dose (not > 1000 mg/dose).

Gonorrhea

PO (Adults): Single 2-g dose.

Prevention of Disseminated MAC Infection

PO (Adults): 1-2 g once weekly (alone or with rifabutin).

PO (Children): 1 mg/kg once daily (not > 250 mg/dose) or 20 mg/kg (not > 1200 mg/dose) once weekly (alone or with rifabutin).

Cystic Fibrosis

PO (Children ≥ 6 yrs, weight ≥ 25 kg to < 40 kg): 250 mg q MWF. 

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PO (Children): 5 mg/kg once daily (not > 250 mg/dose) or 20 mg/kg (not > 1200 mg/dose) once weekly (alone or with rifabutin).

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NURSING IMPLICATIONS

Assessment

● Assess patient for infection (vital signs; appearance of wound, sputum, urine, and stool; WBC) at beginning of and throughout therapy.

● Obtain specimens for culture and sensitivity before initiating therapy. First dose may be given before receiving results.

● Observe for signs and symptoms of anaphylaxis (rash, pruritus, laryngeal edema, wheezing). Notify health care professional immediately if these occur.

● Assess patient for skin rash frequently during therapy. Discontinue azithromycin at first sign of rash; may be life-threatening. Stevens-Johnson syndrome or toxic epidermal necrolysis may develop. Treat symptomatically; may recur once treatment is stopped.

● Lab Test Considerations: May cause q serum bilirubin, ALT, AST, LDH, and alkaline phosphatase concentrations.

● Max. cause: ↑ creatine phosphokinase, potassium, prothrombin time, BUN, serum creatinine, and blood glucose concentrations.

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azithromycin

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- May occasionally cause WBC and platelet count.

Potential Nursing Diagnoses

Risk for infection (Side Effects) (Indications)
Noncompliance (Patient/Family Teaching)

Implementation

- Single double-dose oral suspension is not bioequivalent or inter-changeable with azithromycin oral suspension.
- PO: Administer 1 hr before or 2 hr after meals. Do not use the single packets for administration doses other than 1000 mg of azithromycin.
- For Zmax, shake suspension well and drink entire contents of bottle. Use within 12 hrs of reconstitution. If patient vomits within 1 hr of administration, contact prescriber for instructions. Zmax may be taken without regard to antacids containing magnesium or aluminum hydroxide.

IV Administration

- pH: 6.4–6.6.
- Intermittent Infusion: Diluent: Reconstitute each 500-mg vial with 4.8 mL of sterile water for injection to achieve a concentration of 100 mg/mL. Reconstituted solution is stable for 24 hrs at room temperature. Further dilute the 500-mg dose in 250 mL or 500 mL of 0.45% NaCl, 0.9% NaCl, D5W, LR, 250 mL or 500 mL of 0.9% NaCl with D5W. Concentration: Final concentration of infusion is 1–2 mg/mL. Rate: Administer the 1-mg/mL solution over 3 hr or the 2-mg/mL solution over 1 hr. Do not administer as bolus.

Y-Site Compatibility: acyclovir, abatacept, abemaciclib, aclizumab, acilitubacin, acetazolamide, acetazolamide, acetaminophen, acylglycidyl esters, acylpyridine analogs, acyclovir, acyclovir acylglycerol esters, acyclovir acylglycerol esters, acyclovir acylglycerol esters, acylglycidyl esters, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglycerols, acylglyc
Advise patient to report symptoms of chest pain, palpitations, yellowing of skin or eyes, or signs of superinfection (black, furry overgrowth on the tongue; vaginal itching or discharge; loose or foul-smelling stools) or rash.

Instruct patient to notify health care professional if fever and diarrhea develop, especially if stool contains blood, pus, or mucus. Advise patient not to treat diarrhea without advice of health care professional.

Advise patients being treated for nongonococcal urethritis or cervicitis that sexual partners should also be treated.

Instruct parents, caregivers, or patient to notify health care professional if symptoms do not improve.

Pedi: Tell parents or caregivers that medication is generally well tolerated in children. Most common side effects in children are mild diarrhea and rash. Tell parents to notify health care practitioners if these occur.

**Evaluation/Desired Outcomes**

Resolutions of the signs and symptoms of infection. Length of time for complete resolution depends on the organism and site of infection.

**Why was this drug prescribed for your patient?**