

Name(s)

- **Generic:** azithromycin (az ith roe MYE sin) | **Brand:** Zithromax, Zithromax Tri-Pak, Zithromax Z-Pak

Therapeutic Category

- Antibiotic | **Macrolide**

Dosage Form & Strength

- **PO:** Packet: 1 g | | **Reconstituted Suspension:** 100 mg/5 mL, 200 mg/5 mL | **Tablets:** 250 mg, 500 mg, 600 mg | **Pre-Packaged Tablets:** (Tri-Pak) 500 mg; (Z-Pak) 250 mg | **IV:** **Solution Reconstituted:** 500 mg

Indication(s)

1. **Community Acquired Pneumonia (CAP)**
 2. **Uncomplicated Skin and Skin Structure Infection**
 3. **Streptococcal pharyngitis (Group A)**
 4. **Chronic Obstructive Pulmonary Disease (COPD), Acute Exacerbations**
 5. **Sexually transmitted infections (Cervicitis, Chancroid)**
 6. **Mycobacterium Avium Complex (MAC)**
- OFF-LABEL | (Consult most current literature): Acne vulgaris, Babesiosis, Bronchiectasis (non-cystic fibrosis), prevention of pulmonary exacerbation, Chlamydia, Cholera, COPD exacerbation prevention, many others

Dosing by Indication

1. Adults | Treating **Community Acquired Pneumonia (CAP)**
 - **Outpatient:** 500 mg po on day 1, then 250 mg po qd for 4 days OR 500 mg qd for 3 days
 - **Inpatient:** (IV or PO) 500 mg qd for 3 days (as part of combination therapy)
 - **Pediatrics** | Mild infection or step down therapy in Infants >3 months, Children, Adolescents: 10 mg/kg po once on day 1 (max 500 mg/dose), then 5 mg/kg qd on days 2-5 (max 250 mg/dose) | Severe infection in Infants >3 months, Children, Adolescents: 10 mg/kg **IV** qd for 2 days (max 500 mg/dose), then 5 mg/kg **PO** qd for remainder of 5 day therapy (max 250 mg/dose)
2. Adults | Treating **Uncomplicated Skin and Skin Structure Infection**
 - **For pulmonary, skin, soft tissue, and bone infections:** 250-500 mg po qd (as part of combination therapy). Duration for pulmonary and bone infections is 6-12 months. Duration for skin and soft tissue is at least 4 months.
 - **Pediatrics** | **For susceptible infections:** **PO:** Loading dose of 10-12 mg/kg/dose on day 1 (max 500 mg/dose), then 5-6 mg/kg/dose once daily (max 250 mg/dose) for infection appropriate duration. **IV:** 10 mg/kg once daily with max for 500 mg/dose.
 - **Pediatrics** | **Acute otitis media (AOM):** Infants ≥6 months, Children, Adolescents: 30 mg/kg as single dose (max 1500 mg/dose) OR 10 mg/kg for 3 days (max 500 mg/dose) OR 10 mg/kg on day 1 (max 500 mg/dose) then 5 mg/kg on days 2-5 (max 250 mg/dose).
 - **Pediatrics** | **Bacterial rhinosinusitis:** Infants ≥6 months, Children, Adolescents: 10 mg/kg/dose for 3 days (max 500 mg/dose).
3. Adults | Treating **Streptococcal pharyngitis (Group A)**



- **As an alternative for patients with severe PCN allergy:** 500 mg on day 1, then 250 mg po qd on days 2-5 OR 500 mg po qd for 3 days.
- **Pediatrics** | 12mg/kg/dose once daily for 5 days; max 500 mg/dose OR 12 mg/kg on day 1 (max 500 mg/dose) then 6 mg/kg/dose qd on days 2-5 (max 250 mg/dose). A 3 day regimen has limited data for 20 mg/kg/dose qd for 3 days (max 1000 mg/dose).
- 4. Adults | Treating **Chronic Obstructive Pulmonary Disease (COPD), Acute Exacerbation**
 - **When treating acute exacerbation:** Avoid in patients with risk factors for poor outcomes or *Pseudomonas* infection. Initiate 500 mg loading dose po once on day 1, then 250 mg po qd on days 2-5 OR 500 mg po once daily for 3 days.
 - OFF LABEL | When preventing COPD as exacerbation as well as an anti-inflammatory in cystic fibrosis patients: 250-500 mg po three times weekly OR 250 mg once daily.
 - **Pediatrics** | **Cystic fibrosis to reduce exacerbation and improve lung function:** Children ≥6 years of age and adolescents: **18-35.9 kg:** 250 mg three times weekly (M, W, F) | **≥36 kg:** 500 mg three times weekly (M, W, F).
- 5. Adults | Treating **Sexually transmitted infections**
 - **Empiric therapy for cervicitis & urethritis:** 1 g po for one dose. IF high risk for gonorrhea give in combination with ceftriaxone.
 - **Treating Chancroid, & Chlamydia, Gonococcal infection (OFF LABEL):** 1 g for one dose (preferably under direct supervision).
- 6. Adults | Treating **Mycobacterium Avium Complex (MAC)**
 - **Disseminated disease in patients w/ HIV:**
 - **Treatment:** 500-600mg po qd (One component of a combination therapy)
 - **Primary prophylaxis in pts w/ CD4 count <50 cells/mm³:** 1.2 g po once a week is the preferred course OR 600 mg twice a week.
 - **Secondary prophylaxis:** 500-600 mg po qd (As part of combination therapy). D/c when pt completes 12 months or more of therapy.
 - **Pediatrics** | **Primary prophylaxis:** 20 mg/kg once weekly (max 1200 mg/dose) OR 5 mg/kg/dose qd (max 250 mg/dose) | **Treatment as alternative to clarithromycin:** 10-12 mg/kg/dose qd (part of combo regimen; max 500 mg/dose). Duration of therapy for at least 12 months. | **Secondary prophylaxis (long-term; alternate to clarithromycin):** 5 mg/kg/dose qd (part of combo). Variable duration between 6-12 months based on symptoms and age.
- OFF-LABEL | (Consult most current literature): **Acne vulgaris (i.e. 500mg qd for 4 days per month for 3 months)**, Babesiosis, Bronchiectasis (non-cystic fibrosis), prevention of pulmonary exacerbation, Chlamydia, Cholera, and many others

Mechanism of Action & Pharmacology

- **Pharmacology:** Inhibition of RNA-dependent protein synthesis. Inhibition occurs at the chain elongation step. Azithromycin binds to the 50S ribosomal subunit. This binding at the subunit blocks transpeptidation.
- **Absorption:** Rapid absorption from GI tract (PO) | **Distribution:** Distributes into skin, lungs, sputum, tonsils, cervix. Poor CSF penetration | **Metabolism:** Hepatic | **Excretion:** PO/IV biliary excretion 50% unchained, 6-14% urine unchanged | **Time to Peak:** PO: IR ~2-3 hours; ER 3-5 hours | **Half-Life Elimination:** ~54.5 hours (Infants,



Children 4 months to 15 years) to 68-72 hours (IR, Adults), 59 hours (ER, Adults). | **Protein Binding** is concentration dependent from 7% to 51%

Special Populations & Considerations

- **Renally Impaired Patients:** Cmax increase to 61% and AUC increases to 35%. Dosing may need to be adjusted
- **Elderly Women:** Cmax was observed to be higher but no change in the accumulation of the drug
- **Pregnancy:** Azithromycin crosses placenta. May be used as alternative antibiotic in unplanned cesarean delivery.

Side Effects

- **General:** Upset stomach, n/v/d, and abdominal pain
- **Serious:** Hearing changes, eye problems like blurred vision, heart rhythm changes (QT prolongation), and *C.diff* infection is a concern.

Drug Interactions

- **Concerns w/ an increased risk for irregular heart rhythm such as QT prolongation:** Amiodarone, chloroquine, dofetilide, procainamide, sotalol, haloperidol and others.
- **Concerns w/ P-glycoprotein/ABCB1 inhibitors which may increase following drug concentrations for:** Morphine, nadolol, lapatinib, everolimus, doxorubicin, ubrogepant and others.

Monitoring Parameters

- LFTs, CBC with differential

Patient Counseling Information

- Azithromycin is used in both the treatment and prevention of various **bacterial infections**.
- Can be taken **with or w/o food**. However, **food may decrease any uncomfortable GI distress**.
- Regarding the **reconstituted suspension**: It must be **used w/in 10 days** after reconstitution and it **does not need to be refrigerated** (storage between 41-86 F).

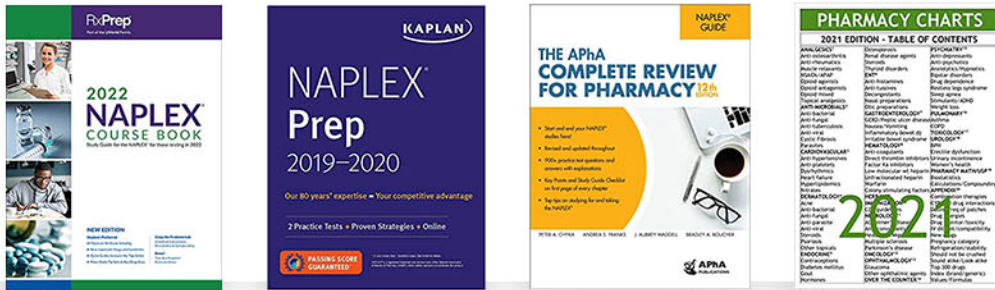
Reference(s)

- <https://www.drugs.com/ppa/azithromycin-systemic.html>
- <https://www.webmd.com/drugs/2/drug-1527-5223/azithromycin-oral/azithromycin-suspension-oral/details>

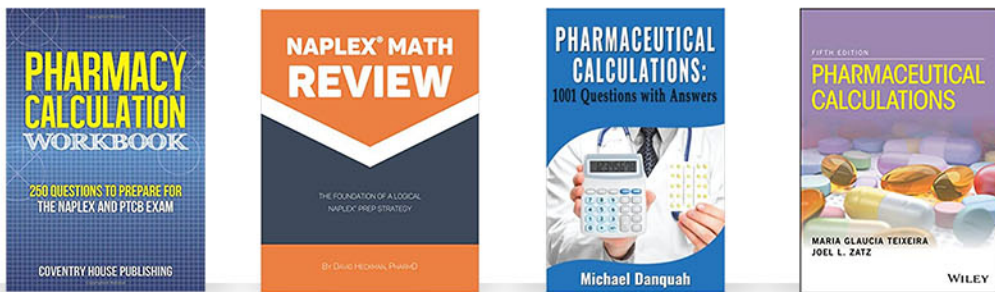


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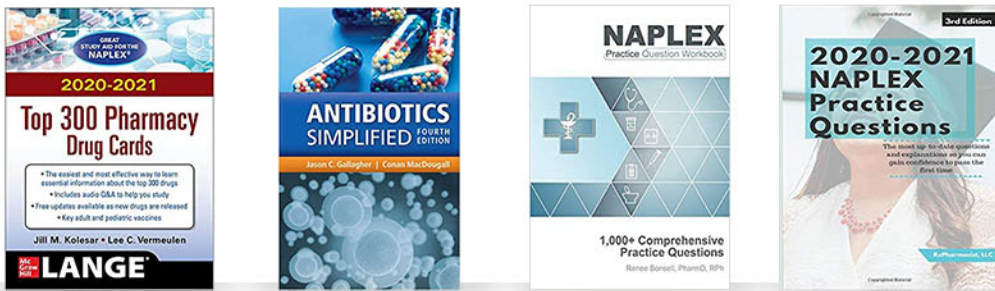
Calculations (NAPLEX)



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