Azithromycin:

Class: Antibiotic

Indications: Oral, I.V.: Treatment of acute otitis media due to *H. influenzae*, *M. catarrhalis*, or *S. pneumoniae*; pharyngitis/tonsillitis due to *S. pyogenes*, community-acquired pneumonia due to *Chlamydia pneumonia*, *H. influenzae*, *M. pneumoniae*, or *S. pneumoniae*; pelvic inflammatory disease (PID) due to *C. trachomatis*, *N. gonorrhoeae*, or *M. hominis*; genital ulcer disease (in men) due to *H. ducreyi* (chancroid); acute bacterial exacerbations of chronic obstructive pulmonary disease (COPD) due to *H. influenzae*, *M. catarrhalis*, or *S. pneumoniae*; acute bacterial sinusitis due to *H. influenzae*, *M. catarrhalis*, or *S. pneumoniae*; prevention of *Mycobacterium avium* complex (MAC) (alone or in combination with rifabutin) in patients with advanced HIV infection; treatment of disseminated MAC (in combination with ethambutol) in patients with advanced HIV infection; skin and skin structure infections (uncomplicated) due to *S. aureus*, *S. pyogenes*, or *S. agalactiae*; urethritis and cervicitis due to *C. trachomatis* or *N. gonorrhoeae*.

Available dosage form in the hospital: 200MG/5ML SUSP. 15ML BOTT, 200MG/5ML SUSP. 30ML BOTTLE, 250MG CAP, 500MG CAP, 300MG/7.5ML SUSP. 22.5ML BOTT, 500MG VIAL.

Trade Names:

Dosage:

- Babesiosis (unlabeled use): Oral: 500-1000 mg on day 1, followed by 250 mg once daily for 7-10 days with atovaquone; higher doses may be required in immunocompromised patients (600-1000 mg daily). Note: Relapsing infection may require at least 6 weeks of therapy (Vannier, 2012; Wormser, 2006).

- Bacterial sinusitis: Oral: 500 mg daily for a total of 3 days

Extended release suspension (Zmax®): 2 g as a single dose

- Cat scratch disease (unlabeled use): Oral: >45.5 kg: 500 mg as a single dose, then 250 mg once daily for 4 additional days (Bass, 1998; Stevens, 2005)

- Chancroid due to *H. ducreyi*: Oral: 1 g as a single dose (CDC, 2010)

- *C. trachomatis* urethritis/cervicitis: Oral: 1 g as a single dose

- Community-acquired pneumonia:
  - Oral: 500 mg on day 1 followed by 250 mg once daily on days 2-5
  - Extended release suspension (Zmax®): 2 g as a single dose

- I.V.: 500 mg as a single dose for at least 2 days, follow I.V. therapy by the oral route with a single daily dose of 500 mg to complete a 7- to 10-day course of therapy.

- Disseminated *M. avium* complex disease in patients with advanced HIV infection: Oral:
Treatment: 600 mg daily in combination with ethambutol

- **Primary prophylaxis:** 1200 mg once weekly (preferred), with or without rifabutin or alternatively, 600 mg twice weekly (CDC, 2009)

- **Secondary prophylaxis:** 500-600 mg daily in combination with ethambutol (CDC, 2009)

-Gonococcal infection, uncomplicated (cervix, rectum, urethra) (unlabeled regimen): Oral: 1 g as a single dose in combination with ceftriaxone (preferred) or cefixime (only if ceftriaxone unavailable); if cefixime is used, test-of-cure in 7 days is recommended (CDC, 2012). Note: Monotherapy with azithromycin single dose of 2 g has been associated with resistance and/or treatment failure; however, may be appropriate for treatment of a gonococcal infection in pregnant women who cannot tolerate a cephalosporin (CDC, 2010).

- **Patients with severe cephalosporin allergy:** 2 g as a single dose and test-of-cure in 7 days (CDC, 2012)

-Gonococcal infection, uncomplicated (pharynx) (unlabeled use): 1 g as a single dose in combination with ceftriaxone (CDC, 2012)

-Gonococcal infection, expedited partner therapy (unlabeled use): Oral: 1 g as a single dose in combination with cefixime (CDC, 2012). Note: Only used if a heterosexual partner cannot be linked to evaluation and treatment in a timely manner; dose delivered to partner by patient, collaborating pharmacy, or disease investigation specialist.

-Granuloma inguinale (donovanosis) (unlabeled use): Oral: 1 g once a week for at least 3 weeks (and until lesions have healed) (CDC, 2010)

-Mild-to-moderate respiratory tract, skin, and soft tissue infections: Oral: 500 mg in a single loading dose on day 1 followed by 250 mg daily as a single dose on days 2-5

  **Alternative regimen:** Bacterial exacerbation of COPD: 500 mg daily for a total of 3 days

-M. genitalium infections (unlabeled use) (confirmed cases in males or females or clinically significant persistent urethritis in males): Oral: 1 g as a single dose or 500 mg on day 1, followed by 250 mg daily on days 2-5 (Manhart, 2011):

  Note: Follow up patients on either regimen in 3-4 weeks for test of cure; consider moxifloxacin for treatment failures (Manhart, 2011)

-Pelvic inflammatory disease (PID): I.V.: 500 mg as a single dose for 1-2 days, follow I.V. therapy by the oral route with a single daily dose of 250 mg to complete a 7-day course of therapy.

-Pertussis (unlabeled use; CDC, 2005): Oral: 500 mg on day 1 followed by 250 mg daily on days 2-5 (maximum: 500 mg daily)

-Pharyngitis, group A streptococci in penicillin-allergic patients (IDSA guidelines): Oral: 12 mg/kg once daily (maximum: 500 mg daily) for 5 days. Note: Recommended by the Infectious Disease Society of America (IDSA) as an alternative agent for group A streptococcal pharyngitis in penicillin-allergic patients (Shulman, 2012).

-Prevention of pulmonary exacerbations in patients with noncystic fibrosis bronchiectasis (unlabeled use): Oral: 500 mg 3 days per week. Note: Duration of treatment in clinical
trial was 6 months; durations >6 months have not been evaluated. Trial patients had ≥1 exacerbation in the past year, no macrolide treatment for >3 months in the past 6 months, and were screened for nontuberculous mycobacterial infection prior to treatment (Wong, 2012). A more selective approach for patients with functionally mild disease has been suggested (Wilson, 2012).

- **Prophylaxis against infective endocarditis** (unlabeled use): Oral: 500 mg 30-60 minutes prior to the procedure. Note: American Heart Association (AHA) guidelines now recommend prophylaxis only in patients undergoing invasive procedures and in whom underlying cardiac conditions may predispose to a higher risk of adverse outcomes should infection occur. As of April 2007, routine prophylaxis for GI/GU procedures is no longer recommended by the AHA.

- **Prophylaxis against sexually-transmitted diseases following sexual assault** (unlabeled use): Oral: 1 g as a single dose (in combination with a cephalosporin and metronidazole) (CDC, 2010)

- **Shigella dysentery type 1** (unlabeled use): Oral: 1000-1500 mg once daily for 1-5 days (WHO, 2005).

- **Urethritis/cervicitis:** Due to C. trachomatis: 1 gram orally x 1. Due to N. gonorrhoeae: 2 grams orally x 1.

  **Renal Impairment:**
  Use with caution in patients with GFR <10 mL/minute

**Common side effect:** Diarrhea, nausea, Pruritus, rash, Abdominal pain, anorexia, cramping, vomiting

**Pregnancy Risk Factor:** B