

**Wazit<sup>TM</sup>** 250mg  
500mg  
{Azithromycin}  
Tablets U.S.P.

وازت  
(ایزیتھرومائیسن)  
۲۵۰ ملی گرام  
۵۰۰ ملی گرام  
تیبلس یو.ا.س.پی۔



## QUALITATIVE AND QUANTITATIVE COMPOSITION

**Wazit Tablets U.S.P. 250mg:** Each film-coated tablet contains: Azithromycin dihydrate eq. to Azithromycin U.S.P. ....250mg

**Wazit Tablets U.S.P. 500mg:** Each film-coated tablet contains: Azithromycin dihydrate eq. to Azithromycin U.S.P. ....500mg

## DESCRIPTION

Wazit (Azithromycin tablets) contain the active ingredient azithromycin, a macrolide antibacterial drug, for oral administration. Azithromycin is derived from erythromycin; however, it differs chemically from erythromycin in that a methyl-substituted nitrogen atom is incorporated into the lactone ring.

## CLINICAL PHARMACOLOGY

**Mechanism of Action:** Azithromycin is a macrolide antibacterial drug. Azithromycin acts by binding to the 23S rRNA of the 50S ribosomal subunit of susceptible microorganisms inhibiting bacterial protein synthesis and impeding the assembly of the 50S ribosomal subunit. **Pharmacokinetics:**

**Absorption:** Rapidly absorbed (40%) after oral administration. **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.

## INDICATIONS AND USAGE

Wazit (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 *Chlamydia 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 in men due to *Haemophilus ducreyi* (chancroid). Due to the small number of women included in clinical trials, the efficacy of azithromycin in the treatment of chancroid in women has not been established.

**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 *Chlamydia 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.

**Limitations of Use:** Azithromycin should not be used in patients with pneumonia who are judged to be inappropriate for oral therapy because of moderate to severe illness or risk factors such as any of the following:

- patients with cystic fibrosis,
- patients with nosocomial infections,
- patients with known or suspected bacteremia,
- patients requiring hospitalization,
- elderly or debilitated patients, or
- patients with significant underlying health problems that may compromise their ability to respond to their illness (including immunodeficiency or functional asplenia).

## CONTRAINDICATIONS

**Hypersensitivity:** Wazit is contraindicated in patients with known hypersensitivity to azithromycin, erythromycin, any macrolide or ketolide drug. **Hepatic Dysfunction:** Wazit is contraindicated in patients with a history of cholestatic jaundice/hepatic dysfunction associated with prior use of azithromycin.

## INTERACTIONS

Do not use Azithromycin with Nelfinavir, Warfarin, Digoxin (P-gp substrates), Zidovudine and closely monitor when using Azithromycin with Astemizole and alfentanil, Potential Drug-Drug Interactions with Macrolides, Cisapride, Antacids, Ergot, Cyclosporine, Coumarin-Type Oral Anticoagulants

## USE IN SPECIFIC POPULATION

**Pregnancy:** Teratogenic Effects (Category B): Azithromycin should be used during pregnancy only if clearly needed. **Nursing Mothers:** Caution should be exercised as azithromycin is excreted in human breast milk in small amounts.

**Pediatric use:** Safety and effectiveness in the treatment of pediatric patients with acute otitis media, acute bacterial sinusitis and community-acquired pneumonia under 6 months of age have not been established. **Geriatric Use:** Use with caution as

can develop torsades de pointes arrhythmias than younger patients. **Renal impairment:** No dose adjustment is necessary in patients with mild to moderate renal impairment (GFR 10 - 80 ml/min). Caution should be exercised when azithromycin is administered to patients with severe renal impairment (GFR < 10 ml/min) both in adults and children. **Hepatic impairment:** The drug should not be given to patients suffering from severe liver disease.

### PRECAUTIONS

Hypersensitivity, Hepatotoxicity, Infantile Hypertrophic Pyloric Stenosis (IHPS), Exacerbation of Myasthenia Gravis, Use in Sexually Transmitted Infections, Development of Drug-Resistant Bacteria.

### ADVERSE REACTIONS

Anorexia, arthralgia, disturbances in taste, disturbances in vision, dizziness, dyspepsia, flatulence, headache, malaise, paraesthesia, reversible hearing loss (sometimes with tinnitus) after long-term therapy. Anxiety, chest pain, constipation, gastritis, hypoaesthesia, leucopenia, oedema, photosensitivity, sleep disturbances, agitation, Acute renal failure, convulsions, haemolytic anemia, interstitial nephritis, smell disturbances, syncope, thrombocytopenia, tongue discoloration

### DOSAGE AND ADMINISTRATION

Wazit tablets and oral suspension can be taken with or without food. Patients should also be cautioned not to take aluminum- and magnesium-containing antacids and azithromycin simultaneously. The patient should be directed to discontinue azithromycin immediately and contact a physician if any signs of an allergic reaction occur.

### Adult patients:

Infection	Recommended Dose/Duration of Therapy
Pharyngitis/tonsillitis (second-line therapy) Skin/soft tissue (uncomplicated)	500 mg as a single dose on Day 1, followed by 250 mg daily for 4 days. (5-days regimen)
Community -acquired pneumonia (low to moderate severity) Respiratory tract infections, otitis media, skin and Soft tissue infections Acute bacterial exacerbations of chronic obstructive pulmonary disease	500 mg once daily for 3 days, alternatively initially 500 mg once daily for 1 day, then 250 mg once daily for 4 days.
Community -acquired pneumonia (high severity)	INITIALLY BY INTRAVENOUS INFUSION Initially 500 mg once daily for at least 2 days, then (by mouth) 500 mg once daily for a total duration of 7-10 days
Acute bacterial sinusitis	500mg once daily for 3 days
Genital ulcer disease (chancroid) Non-gonococcal urethritis & cervicitis due to Chlamydia trachomatis	One single 1 gram dose
Gonococcal urethritis and cervicitis	One single 2 gram dose
Urethral discharge	500 mg daily for 7-10 days
Mild to moderate typhoid due to multiple-antibiotic resistant organisms	500 mg daily for 7 days
Antibacterial prophylaxis for insertion of intra uterine device penicillin	1 g for 1 dose
<b>Mycobacterial Infections</b>	
Prevention of Disseminated MAC (Mycobacterium avium complex)/infections:	1200 mg taken once weekly. This dose of Wazit may be combined with the approved dosage regimen of rifabutin.
Treatment of Disseminated MAC (Mycobacterium avium complex)/infections:	Wazit should be taken at a daily dose of 600 mg, in combination with ethambutol at the recommended daily dose of 15 mg/kg.  Other antimycobacterial drugs that have shown in vitro activity against MAC may be added to the regimen of azithromycin plus ethambutol at the discretion of the physician or health care provider.

### Pediatric Patients:

Infection	Recommended Dose/Duration of Therapy
Acute bacterial sinusitis (>6 months of age)	10 mg/kg once daily for 3 days.
Community -acquired pneumonia (>6 months of age)	10 mg/kg as a single dose on Day 1, followed by 5mg/kg once daily on Days 2 through 5.
Pharyngitis/tonsillitis (>2 years of age)	12 mg/kg once daily for 5 days.
Prevention of secondary case of invasive group A streptococcal infection in patients who are allergic to penicillin	Child 6 months -11 years: 12 mg/kg once daily (max. per dose 500 mg) for 5 days. Child 12 -17 years: 500 mg once daily for 5 days.
Respiratory tract infections, otitis media, skin & soft tissue infections	For Acute otitis media (>6 months of age) : Total dose is for 3 days, either take 30mg as a single dose or take in divided doses as 10 mg/kg once daily for 3 days or 10 mg/kg as a single dose on Day 1 followed by 5 mg/kg/day on Days 2 through 5. Child 6 months -17 years: 10 mg/kg once daily (max. per dose 500 mg) for 3 days Child 6 months -17 years (body weight 15 -25 kg): 200 mg once daily for 3 days Child 6 months -17 years (body weight 26 -35 kg): 300 mg once daily for 3 days Child 6 months -17 years (body weight 36 -45 kg): 400 mg once daily for 3 days Child 6 months -17 years (body weight 46 kg and above): 500mg once daily for 3 days

**Overdosage:** Adverse reactions experienced at higher than recommended doses were similar to those seen at normal doses particularly nausea, diarrhea, and vomiting. In the event of overdosage, general symptomatic and supportive measures are indicated as required.

### INSTRUCTIONS:

Dosage as directed by the physician.

Store at 20°C - 25°C,

excursions permitted to 15°C - 30°C. Protect from light and moisture.

Keep all medicines out of the reach of Children.

To be sold on the prescription of a registered medical practitioner only.

### PRESENTATION

Wazit (Azithromycin) Tablets U.S.P. 250mg are available in Alu-Alu blister pack of 6's with leaflet.

Wazit (Azithromycin) Tablets U.S.P. 500mg are available in Alu-Alu blister pack of 6's with leaflet.

علامت اور پیکار استعمال:

وازت گولے، جلد، پیشاب کی نالی کے ٹنکھڑے اور کھینچی اکوارڈ ڈیموئیہ کے علاج کے لئے تجویز کردہ ہے۔

بچوں میں وازت، پیشاب کی نالی کے ٹنکھڑے اور کھینچی اکوارڈ ڈیموئیہ میں تجویز کردہ ہے۔

مختلف امراض کے علاوہ سے خود کارڈ آئرن کی دوائی کے مطابق استعمال کریں۔

مضمر امراض:

بھوک نہ ہونا، پیڑوں میں درد، سر درد، پیچھے سینے میں درد، قبض، بندھن میں کمی، جگر کی تڑپ،

اختلاج قلب۔

استعمال کی مدت:

حاصل ہوا تین اور دو روزہ پلانے والی دواؤں میں وازت کا استعمال صرف متناہد آئرن کی دوائی سے ہی کریں۔

بچوں، پالہوں اور گردے کے مریضوں میں دوا کا استعمال احتیاط سے کریں۔

کچھ مریضوں میں دوا کا استعمال متناہد ہے۔

پرکاشات:

خوردگی آئرن کی دوائی کے مطابق استعمال کریں۔

30 سے 25 ذریعہ پیشاب کی نالی پر کھینچنے کے بعد 15 سے 3 ذریعہ پیشاب کی نالی سے

گرنی، درد، قبض اور سینے میں درد، دوا میں کھینچنے سے دور رکھیں۔

صرف رینڈوم ڈاؤن کے نسخے پر فروخت کریں۔

Manufactured by:

**GENIX** Genix Pharma (Pvt.) Ltd.

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Manufactured for:

**DANEEN** Daneen Pharma (Pvt.) Ltd.

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