

# MACAZIT

(Azithromycin)

250mg Capsule & Tablet,  
500mg Tablets  
& 200mg/5ml Suspension

## DESCRIPTION:

**Macazit** is an antibiotic used for the treatment of a number of bacterial infections. This includes middle ear infections, strep throat, pneumonia, traveler's diarrhea, and certain other intestinal infections. It can also be used for a number of sexually transmitted infections, including Chlamydia and gonorrhoea infections. Along with other medications, it may also be used for malaria. It can be taken by mouth or intravenously with doses once per day. The empirical formula is  $C_{38}H_{72}N_2O_{12}$  Molecular Weight 749 g/mol

## COMPOSITION:

### > **Macazit 500mg Tablet**

Each film coated tablet contains:  
Azithromycin dihydrate Eq. to azithromycin .....500mg

### > **Macazit 250mg Tablet**

Each film coated tablet contains:  
Azithromycin dihydrate Eq. to azithromycin .....250mg

### > **Macazit 250mg Capsule**

Each capsule contains:  
Azithromycin dihydrate Eq. to azithromycin .....250mg

### > **Macazit 200mg / 5ml dry suspension**

Each 5ml suspension contains:  
Azithromycin dihydrate Eq. to azithromycin .....200mg

## CLINICAL PHARMACOLOGY:

### Pharmacokinetics

#### Absorption

Bioavailability of azithromycin is 37% following oral administration. Absorption is not affected by food. Macrolide absorption in the intestines is believed to be mediated by P-glycoprotein (ABCB1) efflux transporters

#### Distribution

After oral administration, azithromycin is widely distributed in tissues with an apparent steady-state volume of distribution of 31.1 L/kg

#### Metabolism

The principal route of biotransformation involves N-demethylation of the desosamine sugar or at the 9a position on the macrolide ring.

#### Excretion

Biliary excretion of azithromycin, primarily as unchanged drug, is a major route of elimination. Over a 1 week period, approximately 6% of the administered dose is found as unchanged drug in urine

#### Mechanism of Action

Azithromycin is an azalide, derived from erythromycin, and a member of a subclass of macrolide antibiotics with bactericidal and bacteriostatic activities. Azithromycin reversibly binds to the 50S ribosomal subunit of the 70S ribosome of sensitive microorganisms, thereby inhibiting the translocation step of protein synthesis, wherein a newly synthesized peptidyl tRNA molecule moves from the acceptor site on the ribosome to the peptidyl (donor) site, and consequently inhibiting RNA-dependent protein synthesis leading to cell growth inhibition and cell death.

## INDICATION AND USAGE:

Macazit is used to treat diverse infections, including:

- Prevention and treatment of acute bacterial exacerbations of chronic obstructive pulmonary disease due to H. influenzae, M. catarrhalis, or S. pneumoniae. The benefits of long-term prophylaxis must be weighed on a patient-by-patient basis against the risk of cardiovascular and other adverse effects.
- Community-acquired pneumonia due to C. pneumoniae, H. influenzae, M. pneumoniae, or S. pneumoniae
- Uncomplicated skin infections due to S. aureus, S. pyogenes, or S. agalactiae
- Urethritis and cervicitis due to C. trachomatis or N. gonorrhoeae. In combination with ceftriaxone, azithromycin is part of the United States Centers for Disease Control-recommended regimen for the treatment of gonorrhoea.
- Azithromycin is active as monotherapy in most cases, but the combination with ceftriaxone is recommended based on the relatively low barrier to resistance development in gonococci and due to frequent co-infection with C. trachomatis and N. gonorrhoeae.
- Trachoma due to C. trachomatis
- Genital ulcer disease (chancroid) in men due to H. ducrey
- Acute bacterial sinusitis due to H. influenzae, M. catarrhalis, or S. pneumoniae. Other agents, such as amoxicillin/clavulanate are generally preferred, however.
- Acute otitis media caused by H. influenzae, M. catarrhalis or S. pneumoniae. Azithromycin is not, however, a first-line agent for this condition. Amoxicillin or another beta lactam antibiotic is generally preferred.
- Pharyngitis or tonsillitis caused by S. pyogenes as an alternative to first-line therapy in individuals who cannot use first-line therapy

## DOSAGE AND ADMINISTRATION:

For adults,

**Children and adolescents with a body weight of 45 kg or over:**

500 mg once daily during three days with a total dose of 1500 mg Your doctor may decide to prescribe the total dose of 1500 mg during a period of 5 days, with 500 mg the first day and one tablet of 250 mg on days 2 to 5. For infections of the neck of the womb and urethra caused by Chlamydia trachomatis: One dose of 1000 mg, to be taken one time.

**Children and adolescents under 45 kg:**

30 mg/kg as a single dose or 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.

## WARNINGS AND PRECAUTIONS:

Tell your doctor or pharmacist before taking Macazit if you have or have had any of the following conditions:

- kidney problems
- heart problem
- liver problems: your doctor may need to monitor your liver function or stop the treatment

## DRUG INTERACTIONS:

### Nelfinavir

Co-administration of nelfinavir at steady-state with a single oral dose of azithromycin resulted in increased azithromycin serum concentrations

### Warfarin

Spontaneous post marketing reports suggest that concomitant administration of azithromycin may potentiate the effects of oral anticoagulants such as warfarin

### Potential Drug-Drug Interaction with Macrolides

Interactions with digoxin, colchicine or phenytoin have not been reported in clinical trials with azithromycin

## POSSIBLE SIDE EFFECTS:

No other adverse reactions occurred in patients on the multiple-dose regimens of a Macazit with a frequency greater than 1%. Adverse reactions that occurred with a frequency of 1% or less included the following:

**Cardiovascular:** Palpitations, chest pain.

**Gastrointestinal:** Dyspepsia, flatulence, vomiting, melena, and cholestatic jaundice.

**Genitourinary:** Monilia, vaginitis, and nephritis.

**Nervous System:** Dizziness, headache, vertigo, and somnolence.

**General:** Fatigue

**Allergic:** Rash, pruritus, photosensitivity, and angioedema.

## STORAGE & INSTRUCTIONS:

Keep out of reach of children & Store below 30°C.

Protect from sunlight & moisture

Improper storage may deteriorate the medicine

Do not use this medicine after the expiry date which is stated on the blister.

## METHOD OF RECONSTITUTION FOR DRY POWDER SUSPENSION:

To prepare 15ml suspension add 10ml boiled cooled water to the powder by using the given measuring device and shake. Once prepared should be used within 7 days

## PRESENTATION:

**Macazit 250mg tablet in pack of 6's**

**Macazit 500mg tablet in pack of 6's**

**Macazit 250mg Capsule In Pack of 6 s'**

**Macazit 250mg capsule in pack of 10's**

**Macazit 200mg/5ml dry suspension (15ml) in pack of 1's**

Manufactured by :



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**(PVT.) LIMITED** | Road, Layyah.  
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