

# Maczith

Azithromycin USP

## COMPOSITION

Maczith 250 mg Capsule: Each capsule contains Azithromycin 250 mg as Azithromycin Dihydrate USP.

Maczith 500 mg Tablet: Each film coated tablet contains Azithromycin 500 mg as Azithromycin Dihydrate USP.

Maczith 15 ml, 35 ml & 50 ml Powder for Suspension: After reconstitution, each 5 ml suspension contains Azithromycin 200 mg as Azithromycin Dihydrate USP.

## DESCRIPTION

Maczith (Azithromycin) is a semi-synthetic macrolide antibiotic of the azalide class. Like other macrolide antibiotics, Maczith (Azithromycin) is acid-stable antibiotic so it can be taken orally with no need of protection from gastric acids. It is readily absorbed, but absorption is greater on an empty stomach. Time to peak concentration (T<sub>max</sub>) in adults is 2.1 to 3.2 hours for oral dosage forms and one to two hours after a dose. Due to its high concentration in phagocytes, Maczith (Azithromycin) is actively transported to the site of infection. During active phagocytosis, large concentrations are released. Its effects may be bacteriostatic or bactericidal depending of the organism and the drug concentration. Its long half life, which enables once daily dosing and shorter administration durations, is a property distinct from other macrolides. Azithromycin inhibits the growth of bacteria by interfering with their protein synthesis. It binds to the 50S subunit of the bacterial ribosome, and thus inhibits translation of mRNA. Maczith (Azithromycin) demonstrates activity in vitro against a wide range of Gram-positive and Gram-negative bacteria including: Aerobic and facultative gram-positive microorganisms- *Staphylococcus aureus* (Methicillin-sensitive only), *Streptococcus agalactiae*, *Streptococcus pneumoniae*, *Streptococcus pyogenes*. Aerobic and facultative gram-negative microorganisms- *Haemophilus ducreyi*, *Haemophilus influenzae*, *Moraxella catarrhalis*, *Neisseria gonorrhoeae*, *Bordetella pertussis*, *Legionella pneumophila*. Anaerobic microorganisms- *Peptostreptococcus specie*, *Prevotella bivia*. Other microorganisms- *Chlamydia pneumoniae*, *Chlamydia trachomatis*, *Mycoplasma pneumoniae* & *Ureaplasma urealyticum*.

## INDICATIONS

Azithromycin is indicated for infections caused by susceptible organisms in-

Upper respiratory tract infections including sinusitis, pharyngitis and tonsillitis. Lower respiratory tract infections including bronchitis, acute bacterial exacerbations of chronic obstructive pulmonary disease (COPD). Otitis media, Skin and soft tissue infections including cellulitis, pyoderma, erysipelas, wound infections, Diarrhea, Shigellosis, Sexually transmitted diseases, especially in the treatment of non-gonococcal urethritis and cervicitis due to *Chlamydia trachomatis*, Genital ulcer disease in men due to *Haemophilus ducreyi* (chancroid), Mild or moderate typhoid due to multiple-antibacterial resistant organisms.

## DIRECTION OF PREPARATION OF SUSPENSION

To reconstitute Maczith 15 ml Powder for Suspension, add 10 ml or 2 tea spoonfuls of just boiled and cooled water to the content of the bottle and shake well to mix uniformly. To reconstitute Maczith 35 ml Powder for Suspension, add 25 ml or 5 tea spoonfuls of just boiled and cooled water to the content of the bottle and shake well to mix uniformly. To reconstitute Maczith 50 ml Powder for Suspension, add 35 ml or 7 tea spoonfuls of just boiled and cooled water to the content of the bottle and shake well to mix uniformly. For ease of preparation, add water to the bottle in two proportions. Shake well after each addition until all the powder is in suspension.

## DOSAGE AND ADMINISTRATIONS

Capsule, Tablet and suspension should be taken at least 1 hour before or 2 hour after meal. However, 500 tablet can be taken with or without food. Adults: For lower respiratory tract infections including bronchitis and pneumonia, upper respiratory tract infections including sinusitis and pharyngitis/ tonsillitis, otitis media and skin and soft tissue infections, the total dose of Maczith is 1.5 gm given as 500 mg once daily for 3 days. An alternative to this dosage schedule is that 500 mg once daily on day 1, followed by 250 mg once daily for next 4 days. For sexually transmitted diseases caused by *Chlamydia trachomatis*, the dose of Maczith is 1 gm given as a single dose. Alternatively, 500 mg once daily on day 1, followed by 250 mg once daily for next 2 days may also be given.

Use in the elderly: Normal adult dosage is recommended. Children: The dose of Maczith in children over 6 months of age is 10 mg/kg body weight once daily for 3 days. Alternatively, 10 mg/kg on day 1, followed by 5 mg/kg for next 4 days is also recommended. There is no information on use of Azithromycin on children less than 6 months of

age. For children with body weight 15-25 kg (3-7 years), the dose is 200 mg once daily for 3 days; for body weight 26-35 kg (8-11 years), the dose is 300 mg once daily for 3 days; for body weight 36-45 kg (12-14 years), the dose is 400 mg once daily for 3 days. For body weights over 45 kg, normal adult dosage is recommended.

### **SIDE-EFFECTS**

Maczith (Azithromycin) is well tolerated with a low incidence of side-effects. The side-effects include nausea, vomiting, abdominal discomfort (pain/cramps), flatulence, diarrhea, headache, dizziness and skin rashes which are reversible upon discontinuation of therapy.

### **CONTRAINDICATIONS**

Azithromycin is contraindicated in patients with a known hypersensitivity to Azithromycin, erythromycin or any of the macrolide antibiotics. Because of the theoretical possibility of ergotism, Azithromycin and ergot derivatives should not be co-administered.

### **PRECAUTIONS**

Precaution should be taken in patients with more severe renal impairment.

### **USE IN THE ELDERLY**

Normal adult dosage is recommended.

### **USE IN HEPATIC IMPAIRMENT**

As the liver is the principal route of excretion of Azithromycin, it should not be prescribed in patients with hepatic disease.

### **USE IN RENAL IMPAIRMENT**

No dosage adjustment is recommended for subjects with renal impairment (GFR <80 ml/min).

### **DRUG INTERACTIONS**

Ergot derivatives: Because of the theoretical possibility of ergotism, Maczith and ergot derivatives should not be co-administered.

Antacids: Peak serum levels but not the total extent of absorption is reduced by magnesium and aluminium containing antacids in stomach. Maczith tablets should be taken at least 1 hour before or 2 hours after the antacid.

Digoxin: Macrolides increases the plasma concentrations of digoxin.

Cimetidine: A single dose of Cimetidine administered 2 hours before Maczith had no effect on the pharmacokinetics of Azithromycin.

Warfarin: Azithromycin and warfarin may be co-administered, but monitoring of the prothrombin time should be continued as routinely performed.

### **OVER DOSAGE & TREATMENT**

Typical symptoms of over dosage with macrolide antibiotics include hearing loss, severe nausea, vomiting and diarrhea. Gastric lavage and general supportive measures are indicated.

### **STORAGE CONDITIONS**

Store in a cool and dry place, away from light. Keep out of reach of children.

### **COMMERCIAL PACK**

Maczith 250 Capsule: Each Box containing 6 capsules in Alu-Alu blister pack.

Maczith 500 Tablet: Each Box containing 12 tablets in Alu-Alu blister pack.

Maczith 15 ml Powder for Suspension: Bottle containing dry powder for 15 ml suspension & a measuring cup.

Maczith 35 ml Powder for Suspension: Bottle containing dry powder for 35 ml suspension & a measuring cup.

Maczith 50 ml Powder for Suspension: Bottle containing dry powder for 50 ml suspension & a measuring cup.

Manufactured by



For further query on the use of this medicine, consult to a registered Doctor or Pharmacist.