

# Macrozith®

Azithromycin

## Composition:

**Macrozith® 500 Tablet :** Each film coated tablet contains Azithromycin Dihydrate USP equivalent to Azithromycin 500 mg.

**Macrozith® 15 ml Granules for Suspension:** After reconstitution each 5 ml contains Azithromycin Dihydrate USP equivalent to Azithromycin 200 mg.

**Macrozith® 35 ml Granules for Suspension:** After reconstitution each 5 ml contains Azithromycin Dihydrate USP equivalent to Azithromycin 200 mg.

## Description:

Macrozith® contains Azithromycin Dihydrate USP an azalide, a subclass of macrolide antibiotics, for oral administration. Following oral administration Azithromycin is rapidly absorbed and widely distributed throughout the body. Azithromycin acts by binding to the 50s ribosomal subunit of susceptible microorganisms and thus interfering with microbial protein synthesis. Azithromycin is active against both Gram-positive and Gram-negative microorganisms.

## Indications:

Azithromycin is indicated in lower-respiratory tract infections including bronchitis, community acquired pneumonia, otitis media and in upper respiratory tract infections including sinusitis and pharyngitis/tonsillitis, skin and soft tissue infections, mild to moderate typhoid due to multiple anti-bacterial resistant organisms, chronic obstructive pulmonary disease, cholera in children & adult and sexually transmitted diseases both in male and female. Azithromycin is also indicated for the treatment of uncomplicated genital infections due to *Chlamydia trachomatis* and urethritis and cervicitis due to *Chlamydia trachomatis* and *Neisseria gonorrhoea*.

## Dosage & Administration:

Macrozith® should be given as a single daily dose. In common with many other antibiotics Macrozith® should be taken at least 1 hour before or 2 hours after food.

**Adults:** For the treatment of sexually transmitted diseases caused by *Chlamydia trachomatis*, the dose is 1 g given as a single dose. For all other indications, the dose is 1.5g which should be given as 500mg daily for 3 days.

**Elderly:** Normal adult dose is recommended.

**Children (Child over 6 months) :** 10 mg/kg once daily for 3 days or

| Body Weight | Dose              | Duration |
|-------------|-------------------|----------|
| 15-25 Kg    | 200 mg once daily | 3 days   |
| 26-35 Kg    | 300 mg once daily | 3 days   |
| 36-45 Kg    | 400 mg once daily | 3 days   |

- Uncomplicated gonorrhoea, uncomplicated genital chlamydial infections & non-gonococcal urethritis, 1 g as a single dose
- Typhoid fever, 500 mg once daily for 7 days
- Community acquired pneumonia and chronic obstructive pulmonary disease, 500 mg as a single dose on day 1 followed by 250 mg once daily from day 2 to 5

## Side Effects:

Azithromycin is well tolerated with a low incidence of side effects. Most common side effects are nausea, abdominal discomfort, vomiting, flatulence & diarrhoea.

## Use in Special Group:

**Pregnancy:** Recent clinical studies have recommended that Azithromycin should be considered for the initial treatment of Chlamydial cervicitis in pregnancy. In other infections, it should be used only when clearly needed. It is pregnancy category B drug.

**Lactation :** Caution should be exercised when Azithromycin is administered to a nursing mother.

**Pediatric use:** Azithromycin has been administered to pediatric patients ranging in age from 6 months to 12 years.

## Contraindications:

Azithromycin is contraindicated in patients with known hypersensitivity to Azithromycin or any of the macrolide antibiotics.

## Warning & Precautions :

As with any antibiotic preparation, observation for signs of superinfection with non-susceptible organisms, including fungi is recommended. Caution should be exercised when Azithromycin is administered to subjects with severe renal impairment. Azithromycin is principally metabolized via the liver, so caution should be exercised when Azithromycin is administered to patients with impaired hepatic function.

## Drug Interactions:

Antacids: In patients receiving Azithromycin and antacid, Azithromycin should be taken at least 1 hour before or 2 hours after antacid. Cyclosporin & Digoxin : Macrolides interfere with the metabolism of cyclosporin & digoxin. Ergot derivatives: Because of the theoretical possibility of ergotism, Azithromycin and ergot derivatives should not be co-administered.

## Storage:

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

## Commercial Pack:

**Macrozith® 500 :** 2 x 6's Tablets in Alu-Alu blister pack.

**Macrozith® 15 ml Granules for Suspension :** Each bottle contains dry granules to reconstitute 15 ml of Azithromycin suspension.

**Macrozith® 35 ml Granules for Suspension :** Each bottle contains dry granules to reconstitute 35 ml of Azithromycin suspension.