

# ZITA

## Azithromycin Dihydrate USP

### **Composition :**

ZITA - 500 Tablet : Each Tablet contains Azithromycin USP 500 mg.

ZITA Powder For Suspension : After reconstitution, each 5 ml suspension contains Azithromycin USP 200 mg.

### **Description :**

ZITA contains Azithromycin 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 microorganism.

### **Indications :**

ZITA is indicated for the treatment of infections caused by susceptible organisms in lower respiratory tract infections including bronchitis, pneumonia, otitis media and in upper respiratory tract infections including sinusitis, pharyngitis, tonsillitis, skin and soft tissue infections, sexually transmitted diseases both in men and women. Azithromycin is indicated for the treatment of uncomplicated genital infection due to Chlamydia trachomatis and urethritis and cervicitis due to Chlamydia trachomatis and Neisseria gonorrhoeae.

### **Dosage and Administration :**

ZITA should be taken at least 1 hour before or 2 hours after meal.

Adult : For sexually transmitted disease caused by Chlamydia trachomatis, the dose is 1.0 g as a single dose. For all other indications, the total dose is 1.5 g which should be given as 500 mg daily for 3 days alternatively, initially 500 mg as a single dose, followed by a 250 mg single daily dose for the next 4 days.

Elderly : Normal adult dose is recommended.

Children > 6 months : The dose is 10 mg/kg body-weight as a single daily dose for three days, or for body-weight 15-25 kg, 200 mg or 5 ml/day for 3 days; body-weight 26-35 kg, 300 mg or 7.5 ml/day for 3 days; body-weight 36-46 kg, 400 mg or 10 ml/day for 3 days. Children < 6 months : Not recommended.

### **Contraindications:**

ZITA is contraindicated in patients with known hypersensitivity to Azithromycin or any of the macrolide antibiotics. Because of the theoretical possibility of ergotism, Azithromycin and ergot derivatives should not be co-administered. As with Erythromycin and other macrolides, rare serious allergic reactions including angioneurotic oedema and anaphylaxis have resulted in recurrent symptoms and required a long period of observation and treatment.

### **Side-Effects :**

ZITA is well-tolerated with a low incidence of side-effects. Majority of the side-effects were mild to moderate in nature and of gastro-intestinal in origin with nausea, abdominal discomfort, vomiting, flatulence and diarrhoea. Allergic reaction such as rash has occurred and there have also been rare reports of serious hypersensitivity reactions. Reversible elevation in liver transaminases has been seen with a frequency similar to the comparative macrolides and penicillins used in clinical trials. Transient mild reductions in neutrophil counts have occasionally been observed in clinical trials, although a casual relationship to Azithromycin has not been established.

### **Precautions :**

As with any antibiotic, observation for signs of superinfection with non-susceptible organisms including fungi is recommended. No dosage adjustment is needed in patients with renal impairment.

### **Use in Pregnancy & Lactation :**

Animal reproduction studies have demonstrated that Azithromycin crosses the placenta, but has revealed no evidence of harm to the foetus. There are no adequate and well-controlled study in pregnant women. Since animal reproduction studies are not always predictive of human response, Azithromycin should be used in pregnancy only if adequate alternatives are not available. No data on secretion of Azithromycin in breast milk are available. So, Azithromycin should only be used in lactating women where alternatives are not available.

### **Drug Interactions :**

Azithromycin absorption was reduced in the presence of food and antacid. So, Azithromycin should be administered 1 hour before or 2 hours after taking food or antacid. In patients receiving ergot alkaloids, Azithromycin should be avoided concurrently because of the possibility of ergotism resulting from interaction of Azithromycin with the Cytochrome P-450 system. However, no cases of such interaction have been reported. Macrolides have been known to increase the plasma concentration of digoxin and cyclosporin. There have been no pharmacokinetic drug interactions between Azithromycin and warfarin, theophylline, carbamazepine, methyl prednisolone and cimetidine.

### **Storage :**

Store in a cool (below 30°C), dry place and away from light. Keep out of the reach of children.

### **How Supplied :**

ZITA - 500 Tablet : Box containing 2 X 3 Tablets in Alu-Alu blister pack.

ZITA - Dry Powder For Suspension : Bottle containing dry powder for preparation of 15 ml / 30 ml / 50 ml suspension.

**Manufactured by :**



**KEMIKO PHARMACEUTICALS LTD.**  
BANGLADESH