

# Azithrocin®

Azithromycin

Capsule/Tablet/Powder for Suspension/IV Injection

## Description

Azithrocin® contains Azithromycin Monohydrate USP. It is an azalide antibiotic active against Gram-positive and Gram-negative organisms. Azithromycin interferes with ribosome function in susceptible bacteria by inhibiting the translocation of peptides.

## Indications

Azithrocin® (Azithromycin) is indicated for infections caused by susceptible organisms, in upper respiratory tract infections including sinusitis, pharyngitis and tonsillitis, in lower respiratory tract infections including bronchitis and pneumonia, skin and soft tissue infections, and otitis media. Azithrocin is indicated for pelvic inflammatory disease. Azithrocin is indicated in the treatment of uncomplicated genital infections due to *Chlamydia trachomatis*.

## Dosage and Administration

### Azithrocin Capsule & Tablet & Powder for Suspension:

#### Adult:

Azithrocin® (Azithromycin) should be given as 500 mg once-daily orally for 3 days or as an alternative, given over 5 days with 500 mg on day 1, then 250 mg on days 2-5.

For sexually transmitted diseases caused by *Chlamydia trachomatis* in adults, the dose is 1 g given as a single dose.

Normal adult dose is recommended for elderly patients.

#### For children over 6 months recommended dose is:

10 mg/kg once daily for 3 days; or if body weight is 15-25 kg: 200 mg once daily for 3 days, body weight is 26-35 kg: 300 mg once daily for 3 days, body weight is 36-45 kg: 400 mg once daily for 3 days.

As common with many other antibiotics, Azithrocin® should be taken at least 1 hour before or 2 hours after meal and antacid.

### Azithrocin 500 IV Injection:

(For IV Infusion only):

The recommended dose of Azithromycin for injection for the treatment of adult patients with community-acquired pneumonia due to the indicated organisms is:

500 mg as a single daily dose by the intravenous route for at least two days. Intravenous therapy should be followed by Azithromycin by the oral route at a single, daily dose of 500 mg, administered as two 250-mg tablets to complete a 7 to 10-day course of therapy. The timing of the switch to oral therapy should

be done at the discretion of the physician and in accordance with clinical response.

*The recommended dose of Azithromycin for the treatment of adult patients with pelvic inflammatory disease due to the indicated organisms is:*

500 mg as a single daily dose by the intravenous route for one or two days. Intravenous therapy should be followed by Azithromycin by the oral route at a single, daily dose of 250 mg to complete a 7-day course of therapy. The timing of the switch to oral therapy should be done at the discretion of the physician and in accordance with clinical response. If anaerobic microorganisms are suspected of contributing to the infection, an antimicrobial agent with anaerobic activity should be administered in combination with Azithromycin.

Safety and effectiveness of azithromycin for injection in children or adolescents under 16 years have not been established.

For IV infusion dissolve content of vial in 5 ml 0.9% Sodium Chloride BP infusion (Saloride IV infusion) by shaking vigorously. After reconstitution the total volume would be injected in 250 ml 0.9% Sodium Chloride BP infusion (Saloride IV infusion).

## Contraindications

Azithromycin is contraindicated in patients hypersensitive to Azithromycin or any other macrolide antibiotic. Co-administration of ergot derivatives and Azithromycin is contraindicated. Azithromycin is contraindicated in patients with hepatic diseases.

## Side Effects

Azithromycin 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 reactions such as rash have been occurred and there have also been rare reports of serious hypersensitivity reactions. Reversible elevations in liver transaminases have 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 causal 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 dose adjustment is needed in patients with renal impairment.

## Use in special population

### Pregnancy and Lactation

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

## Pediatric Use

Azithromycin oral dosage forms can be administered to pediatric patients from 6 months of age. Safety and effectiveness of azithromycin for injection in children or adolescents under 16 years have not been established.

## Drug Interaction

Azithromycin absorption was reduced in 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. Therefore, if co-administration is necessary, caution should be exercised and serum level of Digoxin and Cyclosporin should be checked. There have been no pharmacokinetic drug interactions between Azithromycin and Warfarin, Theophylline, Carbamazepine, Methylprednisolone and Cimetidine.

## Overdosage

There is no data on overdosage with Azithromycin. Typical symptoms of overdosage with macrolide antibiotics include hearing loss, severe nausea, vomiting and diarrhoea. Gastric lavage and general supportive measures are indicated.

## Pharmaceutical Precautions

Store below 25°C. Protect from light. Keep out of reach of

children.

For IV infusion: When diluted according to the instructions, azithromycin for injection is stable for 24 hours at or below room temperature 30°C (86°F), or for 7 days if stored under refrigeration 5°C (41° F).

## Commercial Pack

Azithrocin® Capsule: Box containing 1 x 10's blister strip, each capsule contains Azithromycin Monohydrate USP equivalent to 250 mg anhydrous Azithromycin.

Azithrocin® 500 Tablet: Box containing 3 x 3's Alu-Alu form packs. Each film coated tablet contains Azithromycin Monohydrate USP equivalent to 500 mg anhydrous Azithromycin.

Azithrocin® Powder for Suspension: Dry powder in glass bottle for reconstitution into 15 ml, 30 ml & 50 ml of suspension. After reconstitution each 5 ml contains Azithromycin Monohydrate USP equivalent to 200 mg anhydrous Azithromycin.

Azithrocin® IV Injection: Each commercial box containing one vial of lyophilized Azithromycin 500 mg, 250 ml 0.9% Sodium Chloride BP Infusion (Saloride IV Infusion), alcohol pad and an infusion set.



Manufactured by

**BEXIMCO PHARMACEUTICALS LTD.**

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