AZICOS Azithromycin for Oral Suspension USP 200mg/5ml

Composition:
Each 5 ml after reconstitution contains:
Azithromycin Dihydrate USP
Eq. to azithromycin (anhydrous) 200 mg
Excipients: q.s.
Color: Approved color used.

Indication: Azithromycin powder for oral suspension is indicated for the treatment of the following infections, when caused by microorganisms susceptible to azithromycin.
- Upper respiratory tract infections: sinusitis, pharyngitis, tonsillitis.
- Acute otitis media
- Lower respiratory tract infections: acute bronchitis and community-acquired pneumonia
- Mild to moderately severe skin and soft tissue infections
- *Chlamydia trachomatis* infections, urethritis, and cervicitis.

Contraindications: Hypersensitivity to: Azithromycin, other macrolide antibiotics, and any of the excipients.

Side effects: Side effects you should report to your doctor or healthcare professional as soon as possible:
- Allergic reactions such as skin rash, itching or hives, swelling of the face, lips, or tongue
- Confusion, nightmares, or hallucinations
- Dark urine
- Difficulty breathing
- Hearing loss
- Irregular heartbeat or chest pain
- Pain or difficulty urinating
- Redness, blistering, peeling, or loosening of the skin, including inside the mouth.
- White patches or sores in the mouth.
- Yellowing of the eyes or skin. Side effects that usually do not require medical attention (inform your doctor or healthcare professional if they persist or become bothersome):
- Diarrhea,
- Dizziness, drowsiness
- Headache
- Stomach pain or vomiting
- Tooth discoloration
- Vaginal irritation

Drug interactions: This medication may also interact with the following medicines: amiodarone, antacids, cyclosporine, digoxin, dihydroergotamine or ergotamine, nelfinavir, phenytoin, and warfarin.

Pregnancy and breastfeeding: Pregnancy. There are no adequate and well-controlled studies in pregnant women. Animal reproduction studies show placental transfer. No teratogenic effects were observed in reproduction studies in rats. The safety of azithromycin regarding the use of the active substance during pregnancy has not been established. Therefore, azithromycin should not be used during pregnancy, except in life-threatening situations where no suitable alternatives are available.

Breastfeeding: Azithromycin passes into breast milk. As it is unknown whether azithromycin may have adverse effects on the nursing infant, breastfeeding should be discontinued during treatment with azithromycin. Potential risks to the nursing infant include, among others, fungal infections of the mucous membranes and sensitization. It is recommended to discard breast milk during treatment and for up to 2 days after discontinuing treatment. Breastfeeding may be resumed thereafter.

Dosage: As directed by the physician.

Storage: Store in a cool, dark, and dry place below 30ºC. The prepared oral suspension must be used within 5 days.

Reconstitution instructions: Tap the bottle to loosen the powder. Add water (previously boiled and cooled) to the powder up to the mark shown on the bottle. Shake the bottle well to obtain a uniform suspension. Add more water (previously boiled and cooled) up to the mark and shake well again.

Keep medicines out of the reach of children.
SHAKE BEFORE USE.
Presentation: 15 ml bottle.

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