

Ziromin 200mg/5ml Powder for Oral Suspension

Azithromycin 200 mg/5 ml as Azithromycin Dihydrate

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What *Ziromin* is used for

This medicine contains *azithromycin*, which is one of a group of antibiotics called macrolides. It is used to treat infections caused by certain bacteria and other micro-organisms which include:

- Chest, throat or nasal infections (such as bronchitis, pneumonia, tonsillitis, sore throat (pharyngitis) and sinusitis)
- Ear infections
- Skin and soft tissue infections (such as an abscess or boil)
- Sexually-transmitted diseases caused by organisms called *Chlamydia trachomatis* or *Neisseria gonorrhoea*. It is also indicated in the treatment of chancroid due to *Haemophilus Ducreyi*.

How *Ziromin* works

Ziromin is an antibiotic, which belongs to a group of medicines called azalides. The azalides are a sub-class of a group of antibiotics called macrolides. It works by killing or stopping the growth of bacteria causing your infection.

Before you use *Ziromin*

- When you must not use it

- If you/your child are allergic to *azithromycin*, *erythromycin*, or any macrolide or ketolide antibiotic, or to any of the ingredients of this medicine.
- If you have rare hereditary fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency problems

Pregnancy and lactation

Do not take *Ziromin* if you are pregnant or breast-feeding, are planning to

pregnant or think you may be pregnant. Get advice from your doctor or pharmacist before taking any medicine.

- Before you start to use it

Talk to your doctor or pharmacist before taking *Ziromin* if you/your child have or have had any of the following:

- kidney problems
- heart conditions
- diabetes
- liver problems
- or if you are taking any ergot derivatives such as ergotamine (used to treat migraine) as these medicines should not be taken together with *Ziromin*.
- diarrhoea during or after medication
- allergic reaction

- Taking other medicines

Tell your doctor if you use any other medicines, including medicines purchased without a prescription from a pharmacy, supermarket, or health food store. In particular, *Ziromin* may interact with the medicines listed below:

- antacids
- Cetrizine, terfenadine
- Didanosine, zidovudine, efavirenz, indinavir, Nelfinavir
- digoxin
- ergot or ergotamine
- Atorvastatin
- carbamazepine
- cimetidine
- warfarin or any similar medicine to prevent blood clots
- ciclosporin
- Fluconazole
- methylprednisolone
- midazolam, Triazolam
- Rifabutin
- Sildenafil
- theophylline
- Trimethoprim/sulfamethoxazole
- Cisapride
- Astemizole or alfentanil

How to use *Ziromin*

- How much to use

Always take or give this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Shake the bottle well before use. *Ziromin* is usually taken as a single daily dose.

Adults:

For some diseases such as *Chlamydia* and *Haemophilus*, the recommended dose is 1000mg daily taken as a single dose. For gonorrhea, the recommended dose is 1000mg or 2000mg of azithromycin in combination with 250 or 500 mg of ceftriaxone.

For all other indications, the recommended dose is 500mg taken as a single dose, for 3 days. Alternatively, the same total dose can be given over 5 days with 500 mg given on the first day and then 250 mg on days 2 - 5.

Children:

The maximum recommended total dose for any treatment is 1500 mg for children.

In general, the total dose in children is 30mg/kg. For 3 days treatment: 10mg/kg will be given as single dose. For 5 days treatment: 10mg/kg will be given on day 1, then 5mg/kg on days 2 – 5.

Your pharmacist will explain how to use it if you are not sure.

Azithromycin tablets should only be administered to children weighing more than 45 kg.

For children weighing less than 15 kg, azithromycin suspension should be measured as closely as possible.

- When to use it

Use as directed by your doctor or pharmacist. Azithromycin powder for oral suspension can be taken with or without food.

Instruction for Use (pack size [60ml])

Tap the bottle to loosen the powder. Then add 15 ml of boiled and cooled water to the content of the bottle and shake well to mix uniformly. Shake immediately prior to use.

- How long to use it

Continue using this medicine for as long as prescribed by your doctor.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

An overdose is likely to cause similar side effects at normal dose. If you take too much oral suspension, you may get a reversible loss of hearing, severe nausea, vomiting and diarrhoea.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking *Ziromin*.

Tell your doctor immediately if you become pregnant while taking this medication. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from *azithromycin* therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give *Ziromin* to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

Ziromin is not expected to affect your ability to drive or use machines.

Sodium content:

This medicine contains sodium. It should be considered in patients on a controlled sodium diet.

Ziromin containing saccharose

If you have been told by your doctor that you have an intolerance to some sugars, please contact your doctor before taking this medicine. If you are diabetic, you may need to take this into account in your diet.

Side effects

Like all medicines, this medicine can cause side effects although not everybody gets them.

Tell your doctor immediately if you experience any of the following symptoms after taking this medicine as the symptoms can be severe.

Examples of side effects included:

- Low level of neutrophils (a type of white blood cell)
- Hearing impairment (hearing loss, deafness and/or tinnitus)
- Nausea, vomiting, diarrhea, watery and soft stools, abdominal pain, accumulation of gas in the digestive system (flatulence)
- Abnormal liver function
- Rash and swelling of skin
- severe cutaneous adverse reactions (SCARs)
- Local pain and inflammation at the site of infusion
- Yeast infections and inflammation of the vagina
- Low blood platelet count
- Serious allergic reaction that may cause death
- Loss of appetite in food
- Aggressive reaction, nervousness, agitation, and anxiety
- Dizziness, convulsions, headache, hyperactivity, reduced sense of touch or sensation, burning or prickling sensation of skin, drowsiness, and temporary loss of consciousness.

- Taste/smell perversion
- Vertigo
- rapid and irregular heartbeat
- QT prolongation and torsades de pointes
- itching, rash, skin more sensitive to sunlight than normal, swelling of eyelids, face or lips, hives
- Low blood pressure
- Uncommon condition in infants that block food from entering the small intestine
- Indigestion, constipation
- Inflammation of the pancreas
- Inflammation of the large intestine
- Discoloration of the tongue
- Liver inflammation
- Reduced secretion of bile
- Joint pain
- Kidneys suddenly stop working properly
- Lack of energy and strength
- Tiredness or weakness

Ziromin may cause severe allergy and serious skin reactions.

Stop using *Ziromin* and seek medical assistance immediately if you experience any of the following symptoms:

- skin reddening, blisters, rash, fever, sore throat or eye irritation

If you notice that the child vomits and/or irritability with feeding occurs, contact doctor immediately as it may be due to the Infantile Hypertrophic Pylorus Stenosis (IHPS).

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of *Ziromin*

- Storage

Keep out of the reach and sight of children.

Stored below 30°C.

Protect from light and moisture.

Reconstituted suspension should be stored below 30°C and used within 5 days. Discard the reconstituted suspension if more than 5 days.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

White colored, cherry scented, fluid, homogenous granules free from particles in pellet form which constitutes white or off-white suspension after reconstitution with water.

- Ingredients

- Active ingredient(s)

Azithromycin Dihydrate

- Inactive ingredients

Saccharose, sodium phosphate tribasic anhydrous, sodium benzoate, hydroxypropyl cellulose, xanthan gum, cherry flavor, banana flavor

- MAL number:

MAL*****

Manufacturer

World Medicine Ilac San. ve Tic. A.S
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Product Registration Holder

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