

Azicine 250mg Hard Capsule

Azithromycin dihydrate 262mg EQ to 250mg of azithromycin

What is in this leaflet

1. What Azicine is used for
2. How Azicine works
3. Before you use Azicine
4. How to use Azicine
5. While you are using it
6. Side effects
7. Storage and disposal of Azicine
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of revision

What Azicine is used for

Azithromycin is used to treat many different types of infections caused by bacteria, such as respiratory infections, skin infections, ear infections and sexually transmitted diseases.

How Azicine works

It works by killing bacteria or preventing their growth. However, this medicine will not work for colds, flu, or other viral infections.

Before you use Azicine

- When you must not use it

If you are allergic to Azicine or any other macrolide antibiotic such as erythromycin or any of the ingredients listed at the end of this leaflet.
If you think any of these apply to you, or if you are in any doubt at all, consult your doctor before taking this drug.

- Before you start use it

If any of the situations mentioned below apply to you, you should tell your doctor before taking this drug:
Inform your doctor if you suffer from heart, liver or kidney disease.
Let your doctor know if you are pregnant or breastfeeding.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

- Antacids (for indigestion)
- Digoxin (used to treat heart failure)
- Zidovudine (used to treat HIV).
- Ergot or ergotamine (used to treat migraine).
- Ciclosporin (used to suppress the immune system to prevent and treat

rejection of a transplanted organ or bone marrow).

- Terfenadine (for hay fever or a skin allergy).

How to use Azicine

- How much to use

Always take this drug exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

For the treatment of sexually transmitted diseases caused by *Chlamydia trachomatis*, *Haemophilus ducreyi* or susceptible *Neisseria gonorrhea*, the dose is 1000mg (4 capsules) taken all together as a single dose.

The usual dose for all other indications will be 1500mg to be given 500mg (2 capsules) daily for 3 days. As an alternative, 1500mg can be given 500mg (2capsule) on day 1, then 250mg (1 capsule) daily on days 2 to 5.

The dose for prophylaxis against *Mycobacterium Avium Complex* (MAC) infections in patients infected with the Human Immunodeficiency Virus (HIV) is 1200mg once per week.

The dose for treatment of *Disseminated Mycobacterium Avium Complex* (DMAC) in patient with advanced HIV infection is 600mg once a day.

No dosage adjustment is required for elderly, mild to moderate kidney impairment (glomerular filtration rate 10-80ml/min) and liver impairment. Azicine should not be taken by children weighing less than 45 kg.

- When to use it

Take them on an empty stomach at least 1 hour before or 2 hours after food, with plenty of water.

- How long to use it

You should take this drug for as long as your doctor continues to prescribe it.

- If you forget to use it

If you forget to take Azicine take it as soon as you can. Take your next dose at the right time. Do not take a double dose to make up for a forgotten dose.

- If you use too much (overdose)

If you take too much Azicine you may

feel unwell. Tell your doctor or contact your nearest hospital casualty department immediately.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

While you are using it

- Things you must do

- If your doctor has told you to take this medicine as and when you need it, tell your doctor if your symptoms change. Always continue with the course even if you feel better.
- If your symptoms do not improve within a few days, or if they become worse, check with your doctor.

- Things you must not do

If you forget to take Azicine take it as soon as you can. Take your next dose at the right time. Do not take a double dose to make up for a forgotten dose.

- Things to be careful of

Your doctor needs to know before you take Azicine if you have or have had any of the following conditions: Kidney problems, heart conditions, liver problems and if you are taking any ergot derivatives such as ergotamine (used to treat migraine) as these medicines should not be taken together with Azicine.
Tell your doctor immediately if you feel your heart beating in your chest or have an abnormal heartbeat, or get dizzy or faint when taking Azicine. If you develop diarrhoea during or after treatment, tell your doctor at once. Do not take any medicine to treat your diarrhoea without first checking with your doctor.
If your diarrhoea continues, please inform your doctor.

Side effects

Like all medicines, Azicine can cause side effects, although not everybody gets them. If you have any of the following symptoms of a severe allergic reaction stop taking this medicine and tell your doctor immediately. The very common side effects is diarrhea. The common side effects are headache, nausea, vomiting, abdominal discomfort (pain/cramps), change in the quantity of the white blood cells and the

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concentration of bicarbonate in the blood. The uncommon side effects are thrush (candidiasis), vaginal infection, lung infection, fungal or bacterial infections, inflammation of the throat (pharyngitis), stomach flu (gastroenteritis), respiratory disorder, runny nose (rhinitis), oral thrush (oral candidiasis), decrease in the total number of white blood cells, low neutrophil count, increase in the number of eosinophils in the blood, hypersensitivity, swelling (oedema), loss of appetite, nervousness, sleeplessness, dizziness, decrease in sensitivity of taste, abnormal sensation, visual disability, ear disorder, giddiness, rapid heartbeat, hot flush, difficult breathing, nose bleed, constipation, flatulence, indigestion, gastritis, difficulty swallowing, abdominal bloating, belch, mouth ulcer, increased salivary flow, rash, severe itching of the skin, skin inflammation, dry skin, excessive sweating, osteoarthritis, muscle pain, back pain, neck pain, pain or difficult urination, kidneys pain, uterine bleeding at irregular intervals, pain or enlargement in testis, lack of energy, feeling of discomfort, tiredness, chest pain, pain, swelling of body (peripheral oedema), alteration in some blood test parameter, increased in chloride, increased in glucose, increased in platelets, and dry mouth. Azicine may cause severe allergy and serious skin reactions. Stop using Azicine and seek medical assistance immediately if you experience any of the following symptoms: Skin reddening, blisters, rash, fever, sore throat or eye irritation. Call your doctor at once if you have a

serious side effect such as serious allergic reaction which causes swelling of the face or throat, yellowing of the skin or whites of the eyes caused by liver or blood problems.

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 Pyloric Stenosis (IHPS).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor/ pharmacist.

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

Storage and disposal of Azicine

- Storage

The expiry date of this pack is printed on the box. Do not use this pack after this date. Keep all medicines out of reach of children. Store in a well-closed container, in a dry place.

Do not store above 30°C.

Do not use Azicine if you notice any visible sign of deterioration.

- 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

Hard gelatin capsule size No.0, white cap and white body, imprinted logo “” on cap and “Azicine” on the body with edible black ink, containing white powder.

- Ingredients

Active ingredient: One hard gelatin capsule contains azithromycin dihydrate equivalent to 250 mg of azithromycin. Inactive ingredients: Lactose monohydrate, pregelatinised starch sodium lauryl sulfate, povidone K30, croscarmellose sodium and magnesium stearate.

Manufacturer and Product Registration Holder

Manufacturer

STELLAPHARM J.V. CO., LTD. – BRANCH 1 (A Joint Venture Company of Auxilto GmbH, Germany) No. 40 Tu Do Avenue, Vietnam - Singapore Industrial Park, An Phu Ward, Thuan An Town, Binh Duong Province, Vietnam.

Product Registration Holder

Stadpharm Sdn. Bhd. E-9-01, Oasis Square, Ara Damansara, No. 2, Jalan PJU 1A/7A, 47301 Petaling Jaya, Selangor Darul Ehsan, Malaysia.

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