

Information leaflet: Information for the user

Azithromycin Baldacci 500 mg film-coated tablets

Azithromycin

Read all of this leaflet carefully before you start taking this medicine as it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. You must not give it to others. The medicine can harm them even if they have the same signs of illness.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What this leaflet contains:

1. What Azithromycin Baldacci is and what it is used for
2. What you need to know before taking Azithromycin Baldacci
3. How to take Azithromycin Baldacci
4. Possible undesirable effects
5. How to store Azithromycin Baldacci
6. Package Contents and Other Information

1. What Azithromycin Baldacci is and what it is used for

Azithromycin Baldacci belongs to a group of antibiotics called macrolides. It is an antibiotic used to treat infections caused by bacteria in different parts of the body.

Azithromycin Baldacci penetrates into infested tissues, where it is released slowly over time, thus fighting bacteria for several days after taking the last dose.

Which infections are treated with Azithromycin Baldacci?

Azithromycin Baldacci is indicated for the treatment of certain infections caused by sensitive microorganisms, such as: tonsillitis/pharyngitis, sinusitis, bronchitis, pneumonia, acute otitis, skin and soft tissue infections (eg abscesses), as well as sexually transmitted diseases, caused by Chlamydia trachomatis and non-multiresistant Neisseria gonorrhoea.

2. What you need to know before taking Azithromycin Baldacci

Do not take Azithromycin Baldacci

- if you are allergic to azithromycin, another macrolide or ketolide (including erythromycin) or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Azithromycin Baldacci:

- If you have ever had any problems taking another medicine;
- If you have liver problems: your doctor may need to monitor your liver function or stop treatment;
- If you have ever had kidney problems.

Tell your doctor immediately,

- if you have any signs of liver disease such as yellowing of the skin, loss/lack of energy, dark urine or any signs of bleeding or behavioral disturbances, as you may need liver function tests or additional diagnostic tests.
- if you experience palpitations or an abnormal heartbeat, or feel dizzy or faint, or if you suffer from any muscle weakness when taking Azithromycin Baldacci.
- if you develop diarrhea or loose stools during or after treatment, speak to your doctor immediately. Do not take any medicine to treat diarrhea without first contacting your doctor. If your diarrhea persists, tell your doctor.
- if you develop any signs of an allergic reaction, eg rash/wheals, blisters, difficulty in breathing, dizziness, swelling of the face or throat. Stop taking this medicine and seek urgent medical advice. Serious allergic reactions to Azithromycin Baldacci are rare.
- if your newborn child develops vomiting and irritability during feeding

This antibiotic works on certain bacteria, but not all bacteria or fungal (fungal) infections.

Other medicines and Azithromycin Baldacci

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines.

If you are taking any of the following medicines, tell your doctor or pharmacist before taking Azithromycin Baldacci:

- Antacids (used in heartburn or indigestion)
- Warfarin (or another drug that interferes with blood clotting)
- Terfenadine (used to treat hay fever or skin allergy)
- Cyclosporine (used to suppress the immune system to prevent and treat rejection in organ or bone marrow transplants)
- Digoxin (used to treat heart failure)
- Colchicine (used for gout and Familial Mediterranean fever)
- Nelfinavir [used to treat HIV infections (AIDS)]
- Ergotamine (used to treat migraines)
- Atorvastatin (used to lower cholesterol levels)
- Antiarrhythmic drugs (used to treat heart disease)
- Antipsychotic medications (used to treat hallucinations or disordered thinking)
- Antidepressant medications (used in depression)
- Fluoroquinolones (antibiotics used to treat serious bacterial infections).

Azithromycin Baldacci with food and drink

You should take Azithromycin Baldacci tablets with water or another drink, with or without food.

Pregnancy and Breastfeeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

There is no evidence that Azithromycin Baldacci affects the ability to drive or use machines.

Azithromycin Baldacci contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Azithromycin contains glycerol triacetate which can cause headache, upset stomach and diarrhea.

3. How to take Azithromycin Baldacci

Always take this medicine exactly as your doctor or pharmacist has told you. Talk to your doctor or pharmacist if you are not sure.

In adults and children weighing more than 45 kg, the recommended dose for most indications is 500 mg once a day (1 tablet of 500 mg) and the duration of treatment is 3 days.

In the treatment of sexually transmitted diseases caused by *Chlamydia trachomatis* or *Haemophilus ducreyi* the recommended dosage is 1 g administered once (2 tablets of 500 mg), for *Neisseria gonorrhea* the recommended dosage is 1 g or 2 g in combination with 250 mg or 500 mg of ceftriaxone.

Use in children and adolescents

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

Mode and Route of Administration

Oral route.

You should take Azithromycin Baldacci tablets with water or another drink, with or without food.

Most favorable moment for the administration

The drug should be administered, preferably at the same time every day. Azithromycin Baldacci should be taken only once a day.

Average duration of treatment

For Azithromycin Baldacci to be effective, the 3 days of treatment must be completed; however, the action of Azithromycin Baldacci lasts longer.

If you take more Azithromycin Baldacci than you should

If someone (eg a child) accidentally takes too many Azithromycin Baldacci tablets at once, doctor must be contacted immediately.

If you forget to take Azithromycin Baldacci

If you miss a dose, take the medicine as soon as you remember and continue the treatment as planned.

Do not take a double dose to make up for a forgotten tablet.

4. Possible undesirable effects

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

Very common side effects (occur in at least 1 in 10 patients) are:

- Diarrhea

Common side effects (occur in at least 1 in 100 patients) are:

- Headache
- Vomiting, abdominal pain, nausea
- Decreased number of lymphocytes (type of white blood cells), higher number of eosinophils, neutrophils, basophils and monocytes (types of white blood cells)
- Reduced blood bicarbonate

Uncommon side effects (occur in at least 1 in 1000 patients) are:

- Fungal infections in the vagina (thrush) and mouth (aphtha), vaginal infection, pneumonia, fungal infection, bacterial infection, sore throat, abdominal pain and cramps, respiratory disturbance, runny nose and nasal irritation
- Decreased number of white blood cells (leukopenia), decreased number of neutrophils (neutropenia)
- Sudden swelling under the skin and allergic reactions of various severities
- loss of appetite
- Nervousness and difficulty falling asleep
- Dizziness, drowsiness, altered taste (dysgeusia) and tingling, cold and heat in a part of the body (paraesthesia)
- Changes in vision
- Hearing disorders and vertigo
- heart palpitations
- Hot flushes (feeling hot)

- Shortness of breath and nosebleeds (epistaxis)
- Constipation, flatulence, difficulty in digestion (dyspepsia), gastritis, difficulty swallowing (dysphagia), abdominal distention, dry mouth, belching, appearance of mouth ulcers, increased saliva in the mouth
- Rash, itching, hives, dermatitis, very dry skin and excessive sweating
- Sharp pain and stiffness of tendons and muscles, muscle pain, back pain and neck pain
- Painful or difficult urination and kidney pain
- Abnormal bleeding outside the menstrual period and testicular disease
- Swelling located in one part of the body, generalized loss of strength, malaise, fatigue, swelling of the face, chest pain, fever, pain, peripheral swelling
- Altered laboratory test values (e.g. blood or liver tests)

Rare effects (occur in at least 1 in 10000 patients) are:

- Agitation
- Altered liver function, yellowish appearance of skin and eyes
- Severe skin reaction after exposure to light or sun
- A rash that is characterized by the rapid appearance of areas of red skin with small pustules (small blisters filled with white/yellow fluid)-
- Delayed allergic reaction (up to several weeks after exposure) with skin rash and other possible symptoms such as swelling of the face, swollen glands and abnormal laboratory results (eg, liver indicators and increased white blood cell values)

Additional undesirable effects that have been reported during post-marketing experience (frequency not known) are:

- Colic relieved by bowel movements, profuse aqueous diarrhea and dehydration (pseudomembranous colitis)
- Decreased number of platelets, abnormally low level of hemoglobin
- Very pronounced urticaria
- Aggression, anxiety, delusions, hallucinations
- Fainting, seizures, motor hyperactivity, decreased sensitivity to touch, loss of smell or altered sense of smell, loss of taste, localized muscle weakness (Myasthenia gravis)
- Loss of hearing and tinnitus
- Heart rhythm problems, including fast heartbeat, irregular heartbeat
- Low blood pressure (hypotension)
- Inflammation of the pancreas, change in the color of the tongue, severe skin reaction

- Liver failure, liver necrosis
- Failure of kidneys, inflammation in kidneys
- Altered electrocardiogram (ECG) (torsades de pointes and prolonged QT interval)
- Stomach pain associated with diarrhea and fever
- Ease of bruising and bleeding
- Joint pain

Communication of undesirable effects

If you get any side effects, talk to your doctor or pharmacist or nurse, including possible side effects not listed in this leaflet. You can also report undesirable effects directly to INFARMED, I.P. through the contacts below. By reporting side effects, you will help to provide more information about the safety of this medicine.

Website: <http://www.infarmed.pt/web/infarmed/submissaoram>

(preferably) or through the following contacts:

Medicines Risk Management Department

Lisbon Health Park, Av. Brasil 53

1749-004 Lisbon

Tel: +351 21 798 73 73

Medicine Line: 800222444 (free)

E-mail: pharmacovigilancia@infarmed.pt

5. How to store Azithromycin Baldacci

Store at a temperature below 30°C.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the outer carton, after EXP. The expiry date is the last day of the indicated month.

Do not dispose of any medicines down the drain or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Package Contents and Other Information

What Azithromycin Baldacci contains

- The active substance is azithromycin. Each film-coated tablet contains azithromycin dihydrate, equivalent to 500 mg of azithromycin, as the active substance.

- The other components are:

Core excipients: pregelatinized starch, crospovidone, anhydrous calcium hydrogen phosphate, sodium lauryl sulfate, magnesium stearate.

Coating excipients: hydroxypropyl methylcellulose, titanium dioxide, lactose, glycerol triacetate.

What Azithromycin Baldacci looks like and contents of the pack

Azithromycin Baldacci is available in packs of 2 and 3 tablets,

It is possible that not all presentations are marketed.

Marketing Authorization Holder and Manufacturer

Marketing Authorization Holder

Baldacci - Portugal, S.A.

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Manufacturer

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