

**Read all of this leaflet carefully before you start taking this medicine because 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. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours. If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.



**AZID 250 mg film-coated tablets**  
**AZID 500 mg film-coated tablets**  
azithromycin

### What is in this leaflet

1. What **AZID** is and what it is used for
2. What you need to know before you take **AZID**
3. How to take **AZID**
4. Possible side effects
5. How to store **AZID**
6. Contents of the pack and other information

#### 1. What **AZID** is and what it is used for

**AZID** contains azithromycin which belongs to the group of antibacterial medicinal products for systemic use, macrolide. **AZID** is indicated for the treatment of the following infections when known or likely to be due to one or more susceptible microorganisms:

- Upper respiratory tract infections including pharyngitis/tonsillitis, sinusitis and otitis media.
- Lower respiratory tract infections including bronchitis and community-acquired pneumonia
- Skin and soft tissue infections including moderate acne vulgaris, erythema chronicum migrans (first stage of Lyme disease), erysipelas, impetigo and secondary pyoderma.
- Sexually transmitted diseases including uncomplicated genital infections due to *Chlamydia trachomatis*
- Gastric and duodenal infections caused by *Helicobacter pylori*.

#### 2. What you need to know before you take **AZID**

##### Do not use **AZID**

- if you are allergic (hypersensitive) to azithromycin, any other macrolide, such as erythromycin
- if you are allergic to any of the other ingredients of **AZID**

##### Warnings and precautions

Talk to your doctor or pharmacist before taking **AZID** if you:

- have heart conditions
- have severe kidney problems
- have liver problems:

Tell your doctor immediately if you feel your heart beating in your chest or have an abnormal heartbeat, or get dizzy or faint or suffer from any muscle weakness when taking **AZID**.

If you develop diarrhoea or loose stools 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.

##### Other medicines and **AZID**

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

In particular, **AZID** may interact with the medicines listed below:

- warfarin or any similar medicine to prevent blood clots
- ciclosporin (used to suppress the immune system to prevent and treat rejection of a transplanted organ or bone marrow)
- digoxin (used to treat heart failure)
- antacids (for indigestion)
- terfenadine (for hay fever or a skin allergy)
- ergot or ergotamine (used to treat migraine)

##### Pregnancy and breast-feeding

**AZID** is not recommended if you are pregnant or planning to become pregnant. 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.

**AZID** (azithromycin) is excreted in human milk, therefore you should not breast-feed whilst you are taking **AZID**.

It is recommended to discard the milk during treatment and up until 2 days after discontinuation of treatment.

##### Driving and using machines

**AZID** (azithromycin) has not been found to affect on the ability to drive or operate machinery. However, **AZID** may cause side effects such as delirium, hallucinations, dizziness, extreme drowsiness, loss of consciousness, convulsions, that may affect your ability to drive or operate machinery.

#### 3. How to take **AZID**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. **AZID** film-coated tablets should be given as a single daily dose. The tablets should be swallowed preferably with a drink of water, and can be taken with or without food.

##### Adults, including elderly patients and children over 45 kg body weight

In the treatment of upper and lower respiratory tract infections, middle ear infections and skin and soft tissue infections (with exception of erythema migrans):

The total dose of azithromycin is 1500 mg which should be given over three days (one 500 mg film-coated tablet or two 250 mg film-coated tablets as a single dose).

##### Moderate acne vulgaris

In the treatment of moderate acne vulgaris the total dose of 6 g is recommended in following regimen:

One 500 mg tablets once daily over 3 days followed by 500 mg tablet once weekly for the following 9 weeks.

The second week dose should be taken seven days after the first taken tablet and the 8 following doses should be taken in 7 days intervals.

##### Erythema migrans

In the treatment of erythema migrans the total dose is 3 g: 1 g once daily (two 500 mg film-coated tablets as single dose) on the first day, followed by 500 mg once daily (one 500 mg film-coated tablet as single dose) from second to fifth day.

##### Uncomplicated genital infections due to *Chlamydia trachomatis*:

In the treatment of uncomplicated genital infections due to *Chlamydia trachomatis*: 1 g (two 500 mg film-coated tablets) as a single dose.

##### Gastric and duodenal infections caused by *Helicobacter pylori*:

In the treatment of gastric and duodenal infections caused by *Helicobacter pylori*: 1 g once daily (two 500 mg film-coated tablets) in combination with antisecretory and other drugs, according to doctor's decision.

##### Children

**AZID 500 mg** film-coated tablets are suitable only for children of at least 45 kg body weight for whom the adult dose may be used.

##### Severe renal and hepatic impairment

The use of azithromycin in this group of patients is contraindicated.

##### If you take more **AZID** than you should

If you take more **AZID** than you should tell your doctor or contact your nearest hospital casualty department immediately. The typical symptoms of an overdose with macrolide antibiotics include reversible loss of hearing, severe nausea, vomiting and diarrhoea.

##### If you forget to take **AZID**

Missed dose should be taken as soon as possible and the following ones in 24 hour intervals. Do not take a double dose to make up for a forgotten dose.

##### If you stop taking **AZID**

Do not stop taking **AZID** before you talk to your doctor.

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

#### 4. Possible side effects

Like all medicines, AZID can cause side effects. AZID is generally well tolerated.

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

- sudden wheeziness, difficulty in breathing, swelling of eyelids, face or lips, rash or itching (especially affecting the whole body)
- severe or prolonged diarrhoea, which may have blood or mucus in it, during or after treatment with AZID as this may be a sign of serious bowel inflammation
- severe skin rash causing redness and flaking (this could be symptoms of Stevens - Johnson syndrome or toxic epidermal necrolysis)
- rapid or irregular heartbeat
- low blood pressure

**Very common:** may affect more than 1 in 10 people

- diarrhoea

**Common:** may affect up to 1 in 10 people

- headache
- low numbers of lymphocytes (a type of white blood cell),
- higher number of eosinophils (a type of white blood cell)
- low blood bicarbonate
- higher number of a type of white blood cell (basophils, monocytes, neutrophils)

**Uncommon:** may affect up to 1 in 100 people

- vaginal infections, pneumonia, fungal infections, bacterial infection, throat inflammation, stomach inflammation, respiratory disorders, sinus inflammation, fungal infection of the mouth
- reduced number of white blood cells (leukocytes)
- blistering of the skin, hypersensitivity
- loss of appetite
- nervousness, insomnia
- dizziness, severe drowsiness, taste disorder, hips
- visual impairment, ear disorders, vertigo, heart palpitations
- hot flushes, difficulty breathing, nasal bleeding
- constipation, winds, digestive disorders, difficulty swallowing, bloating, dry mouth, wheezing, mouth ulcers, increased secretion of salivary glands
- rash, itching, hives, skin inflammation, dry skin, excessive sweating
- inflammation of joints (osteoarthritis), muscle pain, back pain, neck pain
- painful urination, kidney pain
- abnormal uterine bleeding, testicular disorders
- swelling (edema), general weakness, tiredness, swelling of the face, chest pain, fever, pain, leg swelling
- high blood bicarbonate, sodium level disorder, impaired liver enzymes (visible on blood tests)

**Rare:** may affect up to 1 in 1,000 people

- anxiety
- abnormal liver function, jaundice (yellow skin and scleras), hypersensitivity reaction to light

**Not known:** (frequency can not be estimated on the basis of available data):

- type of colon inflammation (pseudomembranous colitis), decreased platelet count (blood platelets responsible for blood clotting), anemia, allergic reaction
- aggression, anxiety, delirium, hallucinations
- sudden loss of consciousness, convulsions, reduced skin sensitivity, psychomotor hyperactivity, loss of smell, loss of taste, sleep disorders, myasthenia gravis (autoimmune disease characterized by fatigue and muscle weakness)
- hearing loss including deafness and / or buzzing in the ears
- heart rhythm disorders
- inflammation of the pancreas, change of color of the tongue
- impaired liver, inflammation of the liver, significant damage to the liver
- joint pain
- acute renal failure, kidney inflammation

#### Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

#### 5. How to store AZID

**Do not store above 25°C. Store in the original pack.** Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

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.

#### 6. Contents of the pack and other information

##### What AZID contains

Active substance: azithromycin (as dihydrate).

##### AZID 250 mg film coated tablets

Each film-coated tablet contains 250 mg azithromycin as dihydrate.

The other ingredients are: calcium hydrogen phosphate, anhydrous, croscarmellose sodium, pregelatinized starch, copovidone, sodium lauryl sulphate, colloidal silicon dioxide, magnesium stearate.

Film: Opadry II white, purified water.

##### AZID 500 mg film coated tablets

Each film-coated tablet contains 500 mg azithromycin as dihydrate.

The other ingredients are: calcium hydrogen phosphate, anhydrous, croscarmellose sodium, pregelatinized starch, copovidone, sodium lauryl sulphate, colloidal silicon dioxide, magnesium stearate.

Film: Opadry II white, purified water.

##### What AZID looks like and contents of the pack

3 film-coated tablets in a PVC/ PVDC/Al blisters. 1 blister in a carton box.

6 film-coated tablets in a PVC/ PVDC/Al blisters. 1 blister in a carton box.

##### Marketing Authorisation Holder and Manufacturer:

ZADA Pharmaceuticals d.o.o.

Donji Bistarac bb

75300 Lukavac, Bosnia and Herzegovina.

**This leaflet was last revised in:** January, 2017.

**Data of first authorisation / renewal of the authorisation in BiH :**

**AZID 250 mg film coated tablets** Date: 22.03.2017.

**Number:** 04-07.3-2-438/16

**AZID 500 mg film coated tablets** Date: 22.03.2017.

**Number:** 04-07.3-2-439/16