Package leaflet: Information for the patient

Azithromycin Krka 250 mg film-coated tablets
azithromycin

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. See section 4.

What is in this leaflet

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

Azithromycin Krka contains the active substance azithromycin. Azithromycin is an antibiotic that belongs to a group of antibiotics known as macrolides, which block the growth of susceptible bacteria.

Azithromycin Krka is taken for the treatment of the following infections:
Adults and adolescents weighing 45 kg and over
- Infections of the tonsils (tonsillitis) or throat (pharyngitis) caused by streptococcal bacteria
- Bacterial sinus infections (sinusitis)
- Bacterial infections of the middle ear (otitis media)
- Pneumonia (community-acquired pneumonia, not contracted in a hospital)
- Bacterial infections of the skin and underlying tissues
- Infections of urethra and cervix caused by *Chlamydia trachomatis* bacteria.

Adults:
- Bacterial infections in patients with long-term inflammation of the lungs (chronic bronchitis)

2. What you need to know before you take Azithromycin Krka

Do not take Azithromycin Krka
- if you are allergic to azithromycin, erythromycin, any macrolide or ketolide antibiotic, 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 Krka if you have or have had any of the following conditions:
- heart problems (e.g. problems with your heart rhythm or cardiac insufficiency) or low levels of potassium or magnesium in your blood: these conditions may contribute to serious cardiac side effects of azithromycin
- liver problems: your doctor may need to monitor your liver function or stop the treatment
- severe diarrhoea after administration of any other antibiotics
- localised muscle weakness (myasthenia gravis), as the symptoms of this disease may worsen

during treatment
- or if you are taking any ergot derivatives such as ergotamine (used to treat migraine) as these medicines should not be taken together with Azithromycin Krka.

Stop taking this medicine and contact your doctor immediately (see also "Serious side effects" in section 4):
- if you feel you are having an allergic reaction (e.g. difficulty in breathing, swelling of the face or throat, rash, blistering).
- if you notice any of the symptoms as described in section 4 related to serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS) and acute generalised exanthematous pustulosis (AGEP), which have been reported in association with azithromycin treatment.
- if you feel you have an abnormal heartbeat or palpitations, get dizzy or faint when taking Azithromycin Krka.
- if you develop signs of liver problems (e.g. dark urine, loss of appetite or yellowing of the skin or whites of the eyes).
- if you develop severe diarrhoea during or after treatment. Do not take any medicine to treat your diarrhoea without first checking with your doctor. If your diarrhoea continues or reappears within the first weeks after treatment, please also inform your doctor.

Superinfection
Your doctor may observe you for signs of additional bacterial or fungal infections that cannot be treated with Azithromycin Krka (superinfection).

Sexually transmitted infections
Your doctor may test for and exclude a potential infection with syphilis, a sexually transmitted disease that may otherwise progress undetected and be diagnosed delayed. Furthermore, in any case of sexually transmitted bacterial infections your doctor will initiate laboratory follow-up tests to monitor the success of therapy.

Children and adolescents
If you weigh less than 45 kg, other medicinal products containing azithromycin exist that may be more convenient for you to take.

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

Taking Azithromycin Krka same time as some other medicines may result in side effects. Therefore, it is particularly important that you tell your doctor if you are using any of the following medicines:
- Atorvastatin and other medicines from the statins group (to lower blood cholesterol and prevent heart disease, including heart attacks and strokes)
- Ciclosporin (to prevent rejection of organ transplants by the body)
- Colchicine (to treat gout and familial Mediterranean fever)
- Dabigatran (to prevent and treat blood clot formation (anticoagulant))
- Digoxin (to treat heart diseases)
- Warfarin or similar medicines used to thin the blood (anticoagulants)
- Medicines that may cause the heart muscle to take longer to contract and relax than usual (QT prolongation), such as the following:
  - Quinidine, procainamide, dofetilide, amiodarone and sotalol (to treat an irregular heartbeat, including a too fast or too slow heartbeat - cardiac arrhythmia)
  - Pimozide (to treat mental illness)
  - Citalopram (to treat depression)
  - Moxifloxacin and levofloxacin (antibiotics)
  - Cisapride (to treat disorders in the gastrointestinal tract)

- Hydroxychloroquine or chloroquine (to treat autoimmune diseases including rheumatoid arthritis, or to treat or prevent malaria)

Pregnancy and breast-feeding
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.

Pregnancy
Your doctor will decide if you should take this medicine during pregnancy, only after making sure that the benefits outweigh the potential risks.

Breast-feeding
Azithromycin Krka passes into breast milk. Your doctor will decide therefore whether you should stop breast-feeding or should avoid treatment with Azithromycin Krka taking into account both the benefit of breast-feeding for your child and the benefit of therapy for you.

Driving and using machines

Azithromycin Krka has a moderate influence on the ability to drive and use machines. Azithromycin Krka has been reported to cause dizziness, drowsiness and seizures, as well as problems with seeing and hearing in some people. These possible side effects may have an influence on your ability to drive and use machines.

Azithromycin Krka contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially "sodium-free.

3. How to take Azithromycin Krka

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

The amount of Azithromycin Krka that you need to take each day depends on the bacterial infection that you are being treated for and the specific treatment course that your doctor or pharmacist has instructed you to follow.

Adults and adolescents weighing at least 45 kg

Infection	Treatment course with azithromycin
Infections of the tonsils (tonsillitis) or throat (pharyngitis) caused by streptococcal bacteria Bacterial sinus infections (sinusitis) Bacterial infections of the middle ear (otitis media) Bacterial infections in patients with long-term inflammation of the lungs (*chronic bronchitis*)* Pneumonia (community-acquired pneumonia, not contracted in a hospital) # Bacterial infections of the skin and underlying tissues	There is a 3-day or a 5-day treatment course for these infections, and the amount of Azithromycin Krka to take each day is described for these treatment courses below. *3-day treatment course* 500 mg taken once daily for 3 days. *5-day treatment course* 500 mg taken on the first day of treatment and then 250 mg taken once daily for the following 4 days.
Infections of urethra and cervix caused by	1 000 mg taken as a single dose

Chlamydia trachomatis bacteria	
* only for adult patients # for adult patients oral treatment may follow an initial intravenous treatment	

Use in children and adolescents
If your weight is less than 45 kg, ask your doctor or pharmacist as other medicinal products containing azithromycin are also available that may be more appropriate for you.

Method of administration
For oral use.

Azithromycin Krka 250 mg tablets should be taken by mouth as a single daily dose. Tablets should be swallowed whole.

Tablets should be taken with some water.
Tablets may be taken with or without a meal. Taking this medicine just before a meal may help make it easier on your stomach.

If you take more Azithromycin Krka than you should
If you take more Azithromycin Krka than you should then you may feel unwell. Typical signs of an overdose are vomiting, diarrhoea, abdominal pain and nausea. Tell your doctor or contact your nearest hospital emergency department immediately.

If you forget to take Azithromycin Krka
If you forget to take Azithromycin Krka take it as soon as you can, as long as this is at least 12 hours before the next dose is due. If it is less than 12 hours left to your next dose, skip the missed dose and take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Azithromycin Krka
If you stop taking Azythromicyn Krka too soon, the infection may return. Take Azythromicyn Krka for the full time of treatment, even when you begin to feel better.

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

4. Possible side effects

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

Serious side effects
Stop using Azithromycin Krka and seek medical attention immediately if you notice any of the following symptoms:
- sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching especially affecting the whole body (*anaphylactic reaction*, frequency not known)
- rapid or irregular heartbeat (*cardiac arrhythmia or torsades de pointes tachycardia*, frequency not known)
- dark urine, loss of appetite or yellowing of the skin or whites of the eyes, which are signs of liver disorders (*hepatic failure or hepatic necrosis*, frequency not known)
- severe diarrhoea with abdominal cramps, bloody stools and/or fever may mean that you have an infection of the large intestine (*antibiotic-associated colitis*, frequency not known). Do not take medicines against diarrhoea that inhibit the bowel movements (*antiperistaltics*)
- reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (*Stevens-Johnson syndrome or toxic epidermal necrolysis*, frequency not known)
- widespread rash, high body temperature and enlarged lymph nodes (*DRESS syndrome* or *drug*

hypersensitivity syndrome, rare (may affect up to 1 in 1 000 people))
- a red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (*acute generalised exanthematous pustulosis*, rare (may affect up to 1 in 1 000 people))

Other side effects

Very common (may affect more than 1 in 10 people)
- diarrhoea

Common (may affect up to 1 in 10 people)
- headache
- being sick (vomiting), stomach pain, feeling sick (nausea)
- changes in blood test results (*lymphocyte count decreased, eosinophil count increased, basophil count increased, monocyte count increased, neutrophil count increased, blood bicarbonate decreased)*

Uncommon (may affect up to 1 in 100 people)
- thrush (candidiasis) - a fungal infection of the mouth and vagina, other fungal infections
- pneumonia, bacterial infection of the throat, inflammation of the gastrointestinal tract, respiratory disorder, inflammation of the mucous membrane inside the nose, vaginal infection
- changes in the number of white blood cells (*leukopenia, neutropenia, eosinophilia*)
- platelet count increased
- reduction in the proportion of all blood cells in the total blood volume *(hematocrit decreased*)
- allergic reactions, swelling of the hands, feet and face (*angiooedema*)
- lack of appetite
- nervousness, difficulty sleeping (*insomnia*)
- feeling dizzy, feeling drowsy (*somnolence*), change in your sense of taste (*dysgeusia*), sensation of pins and needles or numbness (*paraesthesia*)
- impaired vision
- ear disorder
- spinning sensation (*vertigo*)
- feeling your heartbeat (*palpitations*)
- hot flush
- sudden wheeziness, bleeding from the nose
- constipation, wind, impaired digestion (*dyspepsia*), inflammation of the lining of the stomach (*gastritis*), difficulty in swallowing (*dysphagia*), swollen belly, dry mouth, belching (*eructation*), mouth ulceration, increased salivation
- rash, itching, hives (*urticaria*), dermatitis, dry skin, abnormally increased sweating (*hyperhidrosis*)
- swelling and pain in the joints (*osteoarthritis*), muscle pain, back pain, neck pain
- painful urination (*dysuria*), kidney pain
- menstrual bleeding at irregular intervals (*metrorrhagia*), testicular disorder
- swelling due to fluid retention, especially of the face, ankles and feet (*oedema, face oedema, peripheral oedema*)
- weakness, tiredness, general feeling of being unwell, fever
- chest pain, pain
- abnormal laboratory test results (e.g. blood or liver tests)
- post procedural complication

Rare (may affect up to 1 in 1 000 people)
- feeling irritated
- liver problems, yellowing of the skin or eyes
- increased sensitivity to sunlight

Not known (frequency cannot be estimated from the available data)
- reduced number of red blood cells due to increased cell breakdown which can cause tiredness and pale skin (*haemolytic anaemia*)
- reduction in number of platelets which can lead to bleeding and bruising (*thrombocytopenia*)
- feeling angry, aggressive, feeling of fear and concern (*anxiety*), acute confusional state (*delirium*)
- hallucination
- fainting (*syncope*)
- fits (*seizures*)
- reduced sensation to touch, pain and temperature (*hypoaesthesia*)
- feeling hyperactive
- change in your sense of smell (*anosmia*, *parosmia*)
- total loss of your sense of taste (*ageusia*)
- muscle weakness (*myasthenia gravis*)
- abnormal electrocardiogram (ECG) heart tracing (*QT prolongation*)
- deafness, reduced hearing or ringing in your ears (*tinnitus*)
- low blood pressure
- inflammation of the pancreas causing severe pain in the belly and back *(pancreatitis*)
- your tongue changes colour
- joint pain (*arthralgia*)
- kidney inflammation (*interstitial nephritis*) and kidney failure

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Azithromycin Krka

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 packaging after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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

6. Contents of the pack and other information

What Azithromycin Krka contains
- The active substance is azithromycin.
  Each film-coated tablet contains 250 mg azithromycin (as azithromycin dihydrate).
- The other ingredients (excipients) are microcrystalline cellulose (E460), pregelatinised potato starch, sodium laurilsulfate, hypromellose (E464), croscarmellose sodium (E468), colloidal anhydrous silica (E551) and magnesium stearate (E470b) in the tablet core and hypromellose 5 cP (E464), titanium dioxide (E171) and macrogol 400 in the film coating.
  See section 2 "Azithromycin Krka contains sodium".

What Azithromycin Krka looks like and contents of the pack
The film-coated tablets are white or almost white, capsule-shaped (length: 13.8–14.2 mm, width: 6.3–6.7 mm), inscribed "S19" on one side and blank on the other side.

Boxes of 4 and 6 film-coated tablets in blisters are available.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

Manufacturers
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia
TAD Pharma GmbH, Heinz-Lohmann-Straße 5, 27472 Cuxhaven, Germany

This medicine is authorised in the Member States of the European Economic Area under the following names:

Lithuania, Romania	Azibiot
Bulgaria	АЗИБИОТ
Slovakia	Azibiot NEO
Poland, Ireland, Sweden, Finland, Estonia	Azithromycin Krka
Spain, Italy	Azitromicina Krka
Slovenia	Azitromicin Krka

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