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, the active substance of Azithromycin Krka, is one of the group of macrolide antibiotics. It is to treat a number of infections including:
- acute bacterial infections of the air sinuses,
- acute bacterial ear infections,
- tonsillitis, pharyngitis,
- acute bacterial worsening of chronic bronchitis,
- mild to moderately severe pneumonia,
- mild to moderately severe skin and soft tissue infections e.g. folliculitis, cellulitis, erysipelas,
- infection of the tube that carries urine from the bladder (urethra) or the neck of the womb (cervix) caused by bacteria called *Chlamydia trachomatis.*

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

Do not take Azithromycin Krka
- if you are allergic to azithromycin or to other macrolide (such as erythromycin or clarithromycin) or ketolide antibiotics 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 severe liver problems: your doctor may need to monitor your liver function or stop the treatment;
- if you have certain heart conditions (e.g. severe heart problems, "QT prolongation") or if you take medicines inducing an altered electric function of your heart such as cisapride (used to increase bowel movement) or hydroxychloroquine or chloroquine (used for the treatment of malaria);
- if you have a slow or irregular heartbeat;
- if you have altered electrolyte levels in your blood, especially low potassium and magnesium levels;
- if you are taking other medicines that result in abnormal ECG changes (see section "Other

medicines and Azithromycin Krka");
- if you are taking any ergot derivatives (see section "Other medicines and Azithromycin Krka ") as these medicines should not be taken together with Azithromycin Krka;
- if you have severe kidney problems;
- if you have myasthenia gravis (localised muscle weakness);
- you have nervous (neurological) or mental (psychiatric) problems.

During treatment, tell your doctor immediately:
- if you have serious hypersensitivity reactions with difficulty in breathing, dizziness, swelling of face or throat, rash, wheals, blistering (sometimes fatal). If such symptoms occur **stop taking Azithromycin Krka and contact your doctor immediately**.
- if you notice the signs of liver problems during the treatment (e.g. dark urine, profound loss of appetite or yellowing of the skin or whites of the eyes): **Stop taking this medicine and seek urgent medical advice.**
- if you develop diarrhoea, which may be a sign of a serious bowel inflammation. If you have diarrhoea that is watery or bloody, **call your doctor**. Do not use any medicine to stop the diarrhoea unless your doctor has told you to.
- if you feel your heart beating in your chest or have an abnormal heartbeat, get dizzy or faint, or suffer from muscle weakness when taking Azithromycin Krka.
- if you have a new infection (which may be a sign of an overgrowth of resistant organisms).

Children and adolescents
Azithromycin Krka film-coated tablets are **not** suitable for infants and toddlers (under 2 years of age) and children and adolescents (up to 17 years of age) with a body weight **under 45 kg**.
Information for the administration Azithromycin Krka in children and adolescents over 45 kg can be found in section 3 "How to take Azithromycin Krka".

Other medicines and Azithromycin Krka
Tell your doctor or pharmacist if you are taking, have recently take or might take any other medicines.
It is especially important to tell your doctor or pharmacist if you are taking:
- Medicines known as ergot derivatives e.g. ergotamine or dihydroergotamine (medicines used for migraines or reducing blood flow), since these medicines should not be taken simultaneously with Azithromycin Krka,
- Cyclosporine (a medicine used for skin conditions, rheumatoid arthritis, or following organ transplants),
- Atorvastatin (for treating high levels of cholesterol in the blood),
- Cisapride (used to treat stomach problems),
- Theophylline (for breathing problems),
- Warfarin or other medicines to thin your blood,
- Digoxin (for heart problems),
- Colchicine (used for gout and familial Mediterranean fever),
- Zidovudine, efavirenz, indinavir, nelfinavir, didanosine (for HIV-infections),
- Rifabutin (for HIV-infections or for the treatment of tuberculosis),
- Terfenadine (a medicine for the treatment of allergies),
- Fluconazole (for treating fungal infections),
- Medicines known as antacids (medicinal products neutralising gastric acid). Your Azithromycin Krka tablets should be taken at least one hour before or two hours after you take your antacids,
- Astemizole (a medicine for the treatment of allergies), alfentanil (pain killer),
- Hydroxychloroquine or chloroquine (for the treatment of malaria).

Azithromycin Krka with food and drink
The tablets should be taken with water.
You may take your medicine with or without food as it does not affect the absorption of azithromycin.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have baby, ask

your doctor or pharmacist for advice before taking this medicine.
This medicine **should not be used during pregnancy or breast-feeding** unless this has been discussed with your doctor.

Driving and using machines
This medicine may make you feel dizzy. If you feel dizzy, do not drive or use any tools or machines.

Azythromicyn 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.

For adults and children and adolescents with a body weight of 45 kg or over:

Indication	Dosage
- acute bacterial infections of the air sinuses, - acute bacterial ear infections, - tonsillitis, pharyngitis, - acute bacterial worsening of chronic bronchitis, - mild to moderately severe pneumonia, - mild to moderately severe skin and soft tissue infections	- 500 mg once daily during three days with a total dose of 1500 mg or - 500 mg as a single dose on the first day and 250 mg once daily on days 2 to 5, with a total dose of 1500 mg.
- infections of the neck of the womb and urethra caused by Chlamydia trachomatis	1000 mg as a single dose

Children and adolescents with a body weight under 45 kg:
The tablets are not recommended. Children and adolescents with a body weight of less than 45 kg should use other forms of azithromycin containing medicine.

Patients with kidney or liver problems:
You should tell your doctor if you have kidney or liver problems as your doctor may need to alter the normal dose.

Dosage for elderly:
For elderly the same dosage as for adults applies.

Administration:
Swallow the film-coated tablets unchewed with some water.
You may take your medicine with or without food as it does not affect the absorption of azithromycin.

If you take more Azithromycin Krka than you should
It is important to stick to the dose your doctor prescribed you. If you or someone else swallowed several of these tablets all together, or you think a child has swallowed any of these tablets, contact your doctor, pharmacist or hospital emergency department immediately. Always take any tablets left over with you and also the box, as this will allow easier identification of the tablets. Symptoms of overdose may include severe nausea, vomiting and diarrhoea and reversible loss of hearing.

If you forget to take Azithromycin Krka
Do not take a double dose to make up for a forgotten dose. If a dose is forgotten, it should be taken as soon as you remember. However if it is nearly time for the next dose, miss the forgotten dose altogether and continue with the rest of the medicine as normal.

If you stop taking Azithromycin Krka
Do not stop treatment ahead of time.
Even when you start to feel better, it is important for you to keep on taking your tablets for as long as your doctor tells you.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. These are usually mild to moderate, and stop when treatment is stopped.

If you have any of the following symptoms of a severe allergic reaction **stop taking your tablets and either tell your doctor as soon as possible or go to your nearest hospital emergency department:**
- low blood pressure, rapid or irregular heartbeat (anaphylactic reaction);
- swelling of the hands, feet, ankles, face, lips, mouth or throat (angioedema);
- problems with swallowing or breathing;
- serious skin reactions including Stevens-Johnson Syndrome (a severe skin rash) and other severe skin rashes which may involve blistering or peeling (toxic epidermal necrolysis).

If you experience any of the following side effects **contact your doctor as soon as possible:**
- diarrhoea that is severe, persistent especially if it has blood or mucus in it (this may be pseudomembranous colitis, an inflammation of the gut);
- dark urine, profound loss of appetite or yellowing of the skin or whites of the eyes, which are signs of hepatic disorders (hepatic failure which has rarely resulted in death, hepatic necrosis), inflammation of the liver (hepatitis).

These are all serious side effects. You may need urgent medical attention. Serious side effects are uncommon (may affect up to 1 in 100 people), or the frequency cannot be estimated from the available data.

<u>Other side effects reported are:</u>

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

Common (may effect up to 1 in 10 people)
- headache
- being sick (vomiting), abdominal pain, feeling sick (nausea)
- changes in the number of white blood cells
- changed some other blood tests (blood bicarbonate decreased)

Uncommon (may affect up to 1 in 100 people)
- thrush (candidiasis) - a fungal infection of the mouth and vagina
- pneumonia, bacterial infection of the throat, inflammation of the gastrointestinal tract, respiratory disorder, inflammation of the mucous membrane inside the nose
- changes in white blood cells (leukopenia, neutropenia, eosinophilia)
- allergic reactions
- lack of appetite (anorexia)
- nervousness, having difficulty sleeping (insomnia)
- feeling dizzy, feeling drowsy (somnolence), change in your sense of taste (dysgeusia), sensation of pins and needles or numbness (paraesthesia)
- visual impairment
- 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), abdominal distension, dry mouth, release of gas from the stomach (eructation), mouth ulceration, salivary hyper secretion
- rash, itching urticaria, dermatitis, dry skin, abnormally increased sweating (hyperhidrosis)
- degenerative joint disease (osteoarthritis), muscle pain, back pain, neck pain
- difficult urination (dysuria), renal pain
- uterine bleeding at irregular intervals (metrorrhagia), testis disorder
- oedema, weakness, general feeling of being unwell, face oedema, chest pain, fever, pain, peripheral oedema
- abnormal laboratory test values (e.g. blood or liver tests)

Rare (may effect up to 1 in 1,000 people)
- feeling irritated
- abnormal hepatic function, yellowing of the skin or eyes
- allergic skin reactions such as being sensitive to sunlight
- skin eruption that is characterised by the rapid appearance of areas of red skin studded with small pustules (small blisters filled with white/yellow fluid)
- drug rash with eosinophilia (increased amounts of a kind of white blood cell) and systemic symptoms such as fever and swollen lymph glands (DRESS syndrome)

Not known (frequency cannot be estimated from the available data)
- reduced number of red blood cells due to increased cell breakdown (haemolytic anaemia); reduction in number of platelets
- feeling angry, aggressive, feeling of fear and concern (anxiety), acute confusional state (delirium), hallucination
- fainting (syncope)
- fits (convulsions)
- reduced sense of touch (hypoaesthesia)
- feeling hyperactive
- change in your sense of smell (anosmia, parosmia)
- lost your sense of taste (ageusia)
- muscle weakness (myasthenia gravis)
- life-threatening irregular heart beat (arrhythmia, torsades de pointes), abnormal ECG heart tracing (QT prolongation)
- hearing impairment including deafness or ringing in your ears
- low blood pressure
- inflammation of the pancreas (pancreatitis)
- your tongue changes colour
- joint pain (arthralgia)
- kidney inflammation (interstitial nephritis) and kidney failure

Adverse reactions possibly or probably related to Mycobacterium Avium Complex (MAC) prophylaxis and treatment (MAC):

Very common (may affect more than 1 in 10 people)
- diarrhoea
- abdominal pain
- feeling sick (nausea)
- wind
- abdominal discomfort
- loose stools

Common (may affect up to 1 in 10 people)
- lack of appetite (anorexia)

- feeling dizzy
- headache
- sensation of pins and needles or numbness (paraesthesia)
- change in your sense of taste (dysgeusia)
- visual impairment
- deafness
- skin rash, itching
- joint pain (arthralgia)
- tiredness

Uncommon (may affect up to 1 in 100 people)
- reduced sense of touch (hypoaesthesia)
- hearing impairment, ringing in your ears
- feeling your heartbeat (palpitations)
- inflammation of the liver (hepatitis)
- serious allergic skin reactions (Stevens-Johnson syndrome)
- skin more sensitive to sunlight than normal
- weakness
- general feeling unwell

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. 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
1. KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia
2. 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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