Package leaflet: Information for the patient

Clarithromycin Krka 250 mg film-coated tablets
Clarithromycin Krka 500 mg film-coated tablets

clarithromycin

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 Clarithromycin Krka is and what it is used for

Clarithromycin belongs to a group of medicine called macrolide antibiotics. Antibiotics stop the growth of bacteria which cause infections.
Clarithromycin Krka is used in adults and children 12 years and older to treat following infections:
- Chest infections such as bronchitis and pneumonia,
- Throat and sinus infections,
- Skin and soft tissue infections,
- *Helicobacter pylori* infections associated with duodenal ulcers.

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

Do not take Clarithromycin Krka if

- you know that you are **allergic** to clarithromycin, other macrolide antibiotics such as erythromycin or azithromycin, or any of the other ingredients in the tablets.
- you are taking medicines called ergot alkaloids, for example ergotamine or dihydroergotamine tablets or use ergotamine inhalers for migraine. Consult your doctor for advice on alternative medicines.
- you are taking medicines called simvastatin or lovastatin (commonly known as statins, used to lower increased blood fats such as cholesterol and triglycerides).
- if you are taking a medicine containing lomitapide.
- you are taking medicines called terfenadine or astemizole (for hay fever or allergies) or cisapride or domperidone (for stomach disorders) or pimozide tablets (for mental health problems) as combining these drugs can sometimes cause serious disturbances in heart rhythm. Consult your doctor for advice on alternative medicines.
- you are taking other medicines which are known to cause serious disturbances in heart rhythm.
- you are taking medicines called ticagrelor, ivabradine or ranolazine (for angina or to reduce the

chance of heart attack or stroke).
- you are taking a medicine called colchicine (for gout).
- you have abnormally low levels of potassium or magnesium in your blood (hypokalaemia or hypomagnesaemia).
- you are taking oral midazolam (a sedative).
- you have any liver and/or kidney problems.
- you or someone in your family has a history of heart rhythm disorders (ventricular cardiac arrhythmia, including torsades de pointes) or abnormality of electrocardiogram (ECG, electrical recording of the heart) called "long QT syndrome".

Clarithromycin Krka 250 mg, 500 mg film-coated tablets are not suitable for use in children under 12 years of age.

Warnings and precautions
Talk to your doctor or pharmacist before taking Clarithromycin Krka.
- if you have heart problems
- if you are pregnant or breast-feeding
- if you need to have intravenous midazolam

If you develop severe or prolonged diarrhoea during or after receiving Clarithromycin Krka, tell your doctor **immediately**, as this could be a symptom of more serious conditions such as pseudomembranous colitis or clostridium difficile associated diarrhoea.

If you develop any symptoms of liver dysfunction such as anorexia (loss of appetite), yellowing of the skin or whites of the eyes, dark urine, itching or tender abdomen, stop taking Clarithromycin Krka and tell your doctor **immediately.**

Talk to your doctor before taking Clarithromycin Krka if you have kidney problems.

Long term use of Clarithromycin Krka may lead to infection with resistant bacteria and fungi.

Children and adolescents
Clarithromycin Krka are not suitable for use in children under 12 years of age.

Other medicines and Clarithromycin Krka
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is especially important if you are taking medicines called;
- digoxin, quinidine or disopyramide (used to treat heart problems). Your heart may need to be monitored (ECG test) or you may need to have blood tests if you take clarithromycin with some medicines used to treat heart problems
- warfarin, or any other anticoagulant e.g. dabigatran, rivaroxaban, apixaban, edoxaban (used to thin your blood). It may be necessary to have blood tests to check that your blood is clotting efficiently
- omeprazole (used for the treatment of indigestion and stomach ulcers) unless your doctor has prescribed it for you to treat *Helicobacter pylori* infection associated with duodenal ulcer
- ergot alkaloids such as ergotamine or dihydroergotamine (for the treatment of migraine)
- colchicine (for the treatment of gout). Your doctor may wish to monitor you
- theophylline (used in patients with breathing difficulties such as asthma)
- terfenadine or astemizole (for hay fever or allergy)
- triazolam, alprazolam or intravenous or oromucosal midazolam (sedatives)
- cilostazol (for poor circulation)
- cisapride, domperidone or cimetidine (for stomach disorders)
- carbamazepine, valproate, phenytoin or phenobarbital (for the treatment of epilepsy)
- methylprednisolone (a corticosteroid)
- vinblastine (for treatment of cancer)
- ciclosporin, tacrolimus or sirolimus (immune suppressants used for organ transplants and severe eczema)

- pimozide or St. John's wort (for mental health problems)
- rifabutin, rifampicin, rifapentine, fluconazole and itraconazole (treatments for infectious diseases)
- verapamil, amlodipine or diltiazem (for high blood pressure)
- tolterodine (for overactive bladder)
- simvastatin and lovastatin (known as HMG-CoA reductase inhibitors for the treatment of high cholesterol)
- ritonavir, efavirenz, nevirapine, atazanavir, saquinavir, etravirine and zidovudine (anti-viral or anti-HIV drugs)
- sildenafil, vardenafil and tadalafil (for impotence in adult males or for use in pulmonary arterial hypertension - high blood pressure in the blood vessels of the lung)
- insulin, repaglinide, rosiglitazone, pioglitazone, or nateglinide (medicines for the treatment of diabetes)
- aminoglycosides (a type of antibiotic) such as gentamycin, streptomycin, tobramycin, amikacin, netilmicin

This is also important if you are taking medicines called:
- hydroxychloroquine or chloroquine (used to treat conditions including rheumatoid arthritis, or to treat or prevent malaria). Taking these medicines at the same time as clarithromycin may increase the chance of getting abnormal heart rhythms and other serious side effects that affect your heart.
- corticosteroids, given by mouth, by injection or inhaled (used to help suppress the body's immune system - this is useful in treating a wide range of conditions).

Please tell your doctor if you are taking oral contraceptive pills and diarrhoea or vomiting occurs, as you may need to take extra contraceptive precautions such as using a condom.

Clarithromycin Krka with food and drink
Clarithromycin Krka may be taken with or without food.

Pregnancy and breast-feeding and fertility
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. The safety of the use of clarithromycin during pregnancy and breast-feeding has not been established. Therefore, it is not recommended for use during pregnancy without carefully considering the benefits versus the risks. Clarithromycin is excreted in breast milk.

Driving and using machines
Clarithromycin Krka may cause dizziness, vertigo, confusion and disorientation. If you are affected do not drive or use machines.

Clarithromycin 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 Clarithromycin 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 chest infections, throat or sinus infections and skin and soft tissue infections:
The usual dose of Clarithromycin Krka film-coated tablets for adults and children over 12 years is 250 mg twice daily 6-14 days, e.g. one Clarithromycin Krka 250 mg film-coated tablet in the morning and one in the early evening. Your doctor may increase the dose to one Clarithromycin Krka 500 mg tablet twice daily in severe infections.
Clarithromycin Krka tablets should be swallowed with at least half a glass of water.

For the treatment of *Helicobacter pylori* infection associated with duodenal ulcers:
There are a number of effective treatment combinations available to treat *Helicobacter pylori* in which Clarithromycin Krka tablets are taken together with one or two other drugs.
These combinations include the following:
a) One Clarithromycin Krka 500 mg tablet taken twice a day together with amoxicillin 1000 mg taken twice a day with lansoprazole 30 mg twice a day.
b) One Clarithromycin Krka 500 mg tablet taken twice a day together with lansoprazole 30 mg twice a day, plus metronidazole 400 mg taken twice a day.
c) One Clarithromycin Krka 500 mg tablet taken twice a day together with amoxicillin, 1000 mg taken twice a day or metronidazole 400 mg taken twice a day plus omeprazole, 40 mg a day.
d) One Clarithromycin Krka 500 mg tablet taken twice a day together with amoxicillin, 1000 mg taken twice a day plus omeprazole, 20 mg taken once a day.
e) One Clarithromycin Krka 500 mg tablet taken three times a day together with omeprazole 40 mg taken once a day.
The treatment combination which you receive may differ slightly from the above. Your doctor will decide which treatment combination is the most suitable for you. If you are unsure which tablets you should be taking or how long you should be taking them for, please consult your doctor for advice.

Use in children and adolescents
Do not give these tablets to children under 12 years. Your doctor will prescribe another suitable medicine for your child.

If you take more Clarithromycin Krka than you should
If you accidentally take more tablets in one day than your doctor has told you to, or if a child accidentally swallows some tablets, contact your doctor or nearest hospital emergency department immediately. An overdose of Clarithromycin Krka tablets is likely to cause vomiting and stomach pains.

If you forget to take Clarithromycin Krka
If you forget to take a dose of your tablets, take one as soon as you remember. Do not take more tablets in one day than your doctor has told you to. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Clarithromycin Krka
Do not stop taking your tablets, even if you feel better. It is important to take the tablets for as long as the doctor has told you to, otherwise the problem might come back.
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.
If you suffer from any of the following at any time during your treatment STOP TAKING your tablets and contact your doctor immediately:
- severe or prolonged diarrhoea, which may have blood or mucus in it. Diarrhoea may occur over two months after treatment with clarithromycin, in which case you should still contact your doctor.
- a rash, difficulty breathing, fainting or swelling of the face and throat. This is a sign that you may have developed an allergic reaction.
- yellowing of the skin (jaundice), skin irritation, pale stools, dark urine, tender abdomen or loss of appetite. These may be signs that your liver may not be working properly.
- severe skin reactions such as blistering of the skin, mouth, lips, eyes and genitals (symptoms of a rare allergic reaction called Stevens-Johnson syndrome/toxic epidermal necrolysis); a red, scaly rash with bumps under the skin and blisters (exanthematous pustulosis). The frequency of this side effect is not known (cannot be estimated from the available data). Rare allergic skin reactions which cause severe illness with ulceration of the mouth, lips and skin which causes severe illness with rash, fever and inflammation of internal organs (DRESS).
- muscle pain or weakness known as rhabdomyolysis (a condition which causes the breakdown of muscle tissue which can result in kidney damage).

Common: may affect up to 1 in 10 people
- difficulty sleeping (insomnia)
- changes in sense of taste
- headache
- stomach problems such as feeling sick, vomiting, stomach pain, indigestion, diarrhoea
- abnormal liver function blood tests
- rash, excessive sweating, flushing

Uncommon: may affect up to 1 in 100 people
- infections of the skin or vagina, yeast infections (thrush)
- change in the level of white blood cells in the blood (which can make infections more likely)
- change in the levels of blood platelets in the blood (increased risk of bruising, bleeding or blood clots)
- allergic reaction
- decreased appetite
- anxiety, nervousness, screaming
- fainting, dizziness, drowsiness, tremor, involuntary movements of the tongue, face, lips or limbs
- spinning sensation (vertigo), ringing in the ears, hearing loss
- fast, pounding heart (palpitations), changes in heart rhythm or heart stopping
- breathing problems (asthma), nosebleed
- blood clot in the lungs
- stomach problems such as bloating, constipation, wind (flatulence), belching, heartburn or anal pain
- inflammation of the lining of the stomach or oesophagus (the tube connecting your mouth with your stomach)
- sore mouth, dry mouth, inflammation of the tongue
- liver problems such as hepatitis or cholestasis which may cause yellowing of the skin (jaundice), pale stools or dark urine
- increase in liver enzymes
- itching, hives, inflammation of the skin
- stiffness, aches or spasms in the muscles
- kidney problems such as raised levels of protein normally excreted by the kidneys or raised levels of kidney enzymes
- fever, chills, weakness, fatigue, chest pain or general feeling of discomfort
- abnormal blood test results

Not known: frequency cannot be estimated from the available data
- infection of the colon
- infection of the skin
- psychotic disorder, confusion, change in sense of reality, depression, loss of bearings (disorientation), hallucinations (seeing things), abnormal dreams (nightmares), manic episodes
- convulsions
- changes or loss in sense of taste and/or smell
- paraesthesia (tingling and burning sensation in the skin, numbness, ‘pins and needles’ sensation)
- deafness
- bleeding
- type of heart rhythm disorder (Torsade de pointes, ventricular tachycardia)
- inflammation of the pancreas
- discoloration of the tongue, tooth discolouration
- liver failure, jaundice (yellowing of the skin)
- rare allergic skin reactions such as DRESS (which causes severe illness with rash, fever and inflammation of internal organs)
- acne
- muscle disease (myopathy)

- inflammation of the kidney (which can cause swollen ankles or high blood pressure) or kidney failure

Consult your doctor immediately if you develop any of these problems or have any other unexpected or unusual symptoms.

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 Clarithromycin 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 medicinal product 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 Clarithromycin Krka contains
- The active substances is clarithromycin.
  250 mg: Each film-coated tablet contains 250 mg clarithromycin.
  500 mg: Each film-coated tablet contains 500 mg clarithromycin.
- The other ingredients are microcrystalline cellulose, croscarmellose sodium, povidone K30, colloidal anhydrous silica, magnesium stearate, talc and stearic acid in the tablet core and titanium dioxide E171, hypromellose, hydroxypropylcellulose, yellow iron oxide E172 and propylene glycol in the film coating. See section 2" Clarithromycin Krka contains sodium".

What Clarithromycin Krka looks like and contents of the pack
250 mg: oval, biconvex, slightly brownish yellow film-coated tablets of 15 to 15.2 mm in length and 8 mm in width.
500 mg: oval, biconvex, slightly brownish yellow film-coated tablets of 19.5 to 19.8 mm in length and 10 mm in width.

Clarithromycin Krka 250 mg is available in blisters containing 10, 12, 14, 16, 20 film-coated tablets.
Clarithromycin Krka 500 mg is available in blisters containing 7, 10, 14, 16, 20, 21 film-coated tablets.

Not all pack sizes may be marketed.

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

This medicine is authorised in the Member States of the Eurpean Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Croatia	Klaritromicin Krka
Belgium, Denmark, Finland, Ireland, Sweden, Iceland	Clarithromycin Krka
Greece	Clarithromycin/Krka
Portugal	Claritromicina TAD
Italy	Claritromicina HCS 250 mg, 500 mg compresse rivestite con film
Malta	Fromilid
Spain	Claritromicina Krka
United Kingdom (Northern Ireland)	Clarithromycin

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Detailed information of the medicine is available on the website of HPRA (www.hpra.ie).