Package leaflet: Information for the user

Klaram LA 500 mg prolonged-release 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 Klaram LA is and what it is used for

Klaram LA contains the active substance clarithromycin. Clarithromycin is an antibiotic belonging to a group of medicines called the macrolides. Antibiotics stop the growth of bacteria (bugs) which cause infections.

Klaram LA are prolonged-release tablets which means that the active substance is released slowly from the tablet so that you only have to take them once a day.

Klaram LA are used in adults and children older than 12 years to treat infections such as:
- Chest infections such as bronchitis and pneumonia.
- Throat infections such as pharyngitis.
- Sinus infections (sinusitis).
- Skin and soft tissue infections such as folliculitis, cellulitis and erysipelas.

2. What you need to know before you take Klaram LA

Do not take Klaram LA
- if you are allergic to clarithromycin or other macrolide antibiotics such as erythromycin or azithromycin or any of the other ingredients of this medicine (listed in section 6).
- if you are taking medicines called ticagrelor, ivabradine or ranolazine (for angina or to reduce the chance of heart attack or stroke)
- if you are taking any of the following consult your doctor for advice on alternative medicines:
  - ergot alkaloids (e.g. ergotamine or dihydroergotamine tablets) or use ergotamine inhalers for migraines.
  - oral midazolam (for anxiety or to help sleep)
  - lovastatin or simvastatin (for high cholesterol).
  - colchicine (for gout)
  - cisapride or domperidone (for stomach disorders), pimozide (for some mental illnesses), terfenadine or astemizole (for hay fever or allergy), as combining these drugs with clarithromycin can sometimes cause serious disturbances in heart rhythm.

- if you are taking other medicines which are known to cause serious disturbances in heart rhythm.
- if you are taking a medicine containing lomitapide
- if you have abnormally low levels of potassium or magnesium in your blood (hypokalaemia or hypomagnesaemia).
- if you or someone in your family has a history of heart rhythm disorders (ventricular cardiac arrhythmia including torsade de pointes) or abnormality of electrocardiogram (ECG, electrical recording of the heart) called "long QT syndrome".
- if you have severe liver problems and/or severe kidney problems.

Be sure to consult your doctor before taking clarithromycin if you think any of these conditions apply to you.

Warnings and precautions
Talk to your doctor or pharmacist before taking Klaram LA
- if you are pregnant or breast-feeding (see Pregnancy and breast-feeding)
- if you develop severe or prolonged diarrhoea during or after taking Klaram LA, consult your doctor immediately
- if you have coronary heart disease, severe cardiac insufficiency, abnormal heart rhythms or clinically relevant slow heartbeat (bradycardia)
- if you have impaired kidney function or impaired hepatic function as a dose reduction may be necessary.

Be sure to consult your doctor before taking clarithromycin if you think any of these conditions apply to you.

Other medicines and Klaram LA
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, as your dose may need to be changed or you may need to have regular tests performed.

Klaram LA must not be taken with ergot alkaloids, astemizole, terfenadine, cisapride, domperidone, pimozide, ticagrelor, ranolazine, colchicine, some medicines for treating high cholesterol and medicines that are known to cause serious disturbances in heart rhythm (see under **Do not take Klaram LA**).

In particular tell your doctor or pharmacist if you are taking any of the following medicines:
- itraconazole or fluconazole (anti-fungal drugs);
- zidovudine, ritonavir, atazanavir, saquinavir, etravirine, nevirapine or efavirenz (anti-viral [anti-HIV] drugs);
- rifabutin (an antibiotic effective against some infections);
- rifampicin and rifapentine (to treat tuberculosis);
- aminoglycosides (medicines used as antibiotics to treat infections);
- digoxin, quinidine, disopyramide, amlodipine, verapamil, diltiazem (heart drugs);
- carbamazepine, valproate, phenobarbital or phenytoin (drugs for epilepsy or bipolar disorder);
- warfarin or any other anticoagulant, e.g. dabigatran, rivaroxaban, apixaban, edoxaban (used to thin your blood);
- quetiapine or ziprasidone (antipsychotics used for schizophrenia or other psychiatric conditions)
- sildenafil, tadalafil or vardenafil (for treating erectile dysfunction);
- theophylline (helps breathing);
- tolterodine (to treat symptoms of overactive bladder syndrome);
- triazolam, alprazolam or intravenous or buccal (oromucosal) midazolam (sedatives used for anxiety or to help sleep);
- omeprazole (for stomach disorders);
- tacrolimus, sirolimus or ciclosporin (for organ transplants);
- methylprednisolone (a corticosteroid to treat inflammation);
- ibrutinib or vinblastine (chemotherapy agents used to treat cancer);
- cilostazol (used to improve circulation in the legs);

- St John's Wort (herbal remedy used to treat depression);
- insulin or oral anti-diabetic medicines such as nateglinide or repaglinide (to reduce blood sugar levels).
- eletriptan (for migraine)
- aprepitant (for preventing vomiting during chemotherapy)
- any betalactam antibiotics (certain penicillins and cephalosporin antibiotics)

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)

Klaram LA with food and drink

Klaram LA should be taken with food and must be swallowed whole and not chewed.

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.

If you are pregnant or breast feeding do not take Klaram LA without consulting your doctor first, as the safety of Klaram LA in pregnancy and breast feeding is not known.

Driving and using machines

As Klaram LA may cause dizziness, confusion and disorientation it may affect your ability to drive or use machinery.

Klaram LA contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Klaram LA

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

Klaram LA should be taken with food and must be swallowed whole and not chewed. You should take each dose at the same time each day throughout your course of treatment.

<u>Adults and children over 12 years</u>
The recommended dose of Klaram LA is one 500 mg prolonged-release tablet once a day for 6 to 14 days.

Your doctor may increase the dose to two 500 mg prolonged-release tablets in severe infections. You should take both of these tablets at the same time.

<u>Children 12 years old and younger:</u>
These tablets are not suitable for children 12 years old and younger. Liquid medicines are therefore generally preferable for children. Your doctor will prescribe another suitable medicine for your child.

Patients with kidney problems:
These tablets are not suitable for patients with kidney problems. Your doctor will prescribe another suitable medicine.

If you take more Klaram LA than you should

If you accidentally take more than you should of Klaram LA or if a child accidentally swallows some tablets, seek medical advice urgently. An overdose of Klaram LA is likely to cause vomiting and stomach pains and there is a possibility of allergic reactions.

If you forget to take Klaram LA

If you forget to take a Klaram LA tablet, take one as soon as you remember. Do not take a double dose to make up for a forgotten dose.

If you stop taking Klaram LA

Do not stop taking Klaram LA because 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 notice any of the following serious side effects, stop taking Klaram LA and contact a doctor immediately:

- Severe or prolonged diarrhoea, which may have blood or mucus in it, stomach pain and fever. Diarrhoea may occur over two months after treatment with clarithromycin.
- A rash, difficulty breathing, fainting or swelling of the face and throat. Contact your doctor immediately as these may be signs of an allergic reaction and may need emergency treatment.
- Loss of appetite, yellowing of the skin (jaundice), dark urine, light-coloured stools, itching or tenderness in the abdomen. Contact your doctor immediately as these may be signs of liver failure.
- Severe skin reactions, potentially life-threatening, such as blistering of the skin, mouth, lips, eyes and genitals (symptoms of a rare allergic reaction called Stevens-Johnson syndrome/toxic epidermal necrolysis) or a red, scaly rash with bumps under the skin and blisters (symptoms of exanthematous pustulosis). The frequency of this side effect is not known (cannot be estimated from the available data).
- Muscle pain or weakness known as rhabdomyolysis (a condition which causes the breakdown of muscle tissue which can result in kidney damage).

Other possible side effects

Common side effects: may affect up to 1 in 10 people
- Insomnia
- Abdominal pain, diarrhoea, vomiting, digestive discomfort and feeling sick.
- Changes in sense of taste (dysgeusia), headache.
- Liver function test abnormal.
- Rash, excessive sweating.

Uncommon side effects: may affect up to 1 in 100 people

- Thrush and vaginal thrush (candidiasis), gastric flu, infections, vaginal infections, inflammation of the skin caused by infections.
- Changes in the numbers of blood platelets (thrombocythemia), neutrophils (neutropenia), or white blood cells (leukopenia).
- Increased number of white blood cells called eosinophils (eosinophilia).
- Anaphylactoid reaction, hypersensitivity.
- Anorexia, decreased appetite.
- Anxiety, nervousness.
- Fainting, dizziness, sleepiness and tremor.
- Ringing in the ears (tinnitus), sensation of spinning or whirling motion (vertigo) and hearing impairment.
- Irregular heart and pulse rate, abnormal electric activity tracing of the heart (ECG), aware of heartbeat (palpitation).
- Asthma, shortness of breath.
- Nosebleed
- Heartburn, inflammation of the stomach, pain in the rectum (proctalgia), inflammation of the inside of the mouth (stomatitis), inflammation of the tongue (glossitis), constipation, swollen stomach (abdominal distension), burping (eructation), dry mouth, flatulence.
- Inflammation of the skin with blisters (dermatitis bullous), itching of the skin, skin rash and hives (urticaria), rash characterized by a flat, red area on the skin that is covered with small confluent bumps (rash maculo-papular).
- Muscle pain, muscle cramps.
- Lack of energy fever, chest pain, chills, mental or physical tiredness, swelling of the face, a feeling of general discomfort, pain and thirst.

Side effects of unknown frequency (frequency cannot be estimated from the available data):

- Bacterial infection of the outer layers of the skin
- Severe acute deficiency in neutrophils (type of blood cells), symptoms include high temperature and ulcers in the mouth and throat (agranulocytosis); reduction of platelets in the blood (thrombocytopenia).
- Sudden allergic reactions (swelling of the face, lips, throat or tongue or difficulty breathing or swallowing), angioedema (swollen face lips throat or tongue). These reactions can be life-threatening and may need emergency treatment.
- Abnormal dreams, confusional state, depersonalization, depression, disorientation, hallucination (seeing things), psychotic disorder, feeling elated or over-excited, which causes unusual behaviour (mania)
- Convulsions, changes in or loss of sense of smell, loss of sense of taste, numbness tingling or pins and needles (paraesthesia).
- Deafness.
- Life-threatening irregular heartbeat, increased heartbeat.
- Bleeding.
- Tongue discolouration, sudden inflammation of the pancreas (upper abdominal pain, going through to the back, which may be associated with loss of appetite, feeling or being sick), tooth discolouration.
- Allergic reactions including rashes. In very rare cases, difficulty in breathing, fainting and swelling of the face and throat can occur which may need emergency treatment. Allergic rashes may range in severity from mild itchy skin eruptions to a rarer, more serious condition called Stevens-Johnson syndrome (which may cause ulceration of the mouth, lips and skin) or toxic epidermal necrolysis (which causes severe illness and sloughing of the skin) or drug rash with eosinophilia and systemic symptoms (DRESS).
- Acne.
- Muscle weakness, tenderness or pain (rhabdomyolysis).
- Kidney failure, inflammation of the kidneys (interstitial nephritis).
- Abnormal colour of the urine.
- Blood clotting time increased (increased INR and prothrombin time).

If you have a blood test while taking Klaram LA it may show a decrease in clotting factor and an increase in other enzymes. Protein in the urine may also be detected.

If you develop diarrhoea during or after taking Klaram LA tablets, consult your doctor immediately. While diarrhoea can occur as a reaction to the medicine, it can also be a sign of a more serious condition. Your doctor will know how to distinguish between the two conditions.

In the unlikely event that your infection has been caused by a germ that Klaram LA cannot treat, your symptoms may get worse. If this happens, be sure to consult your doctor.

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 Klaram LA

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

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the blister and carton after EXP.

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 to protect the environment.

6. Contents of the pack and other information

What Klaram LA contains

- The active substance is clarithromycin. Each prolonged-release tablet contains clarithromycin citrate equivalent to 500 mg of clarithromycin.
- The other ingredients are: *tablet core:* lactose monohydrate, hypromellose, hypromellose phthalate, talc, magnesium stearate; *tablet coat:* hypromellose, lactose monohydrate, quinoline yellow aluminium lake (E104), titanium dioxide (E171), talc, macrogol/PEG 4000, macrogol/PEG 400.

What Klaram LA looks like and contents of the pack

Yellow, oblong shaped, biconvex film-coated tablets, 19.15 ± 0.2mm long, 8.95 ± 0.2mm width and 7.55 ± 0.2mm thick with no markings.

PVC/PVDC/Aluminium blister strip(s) in a cardboard carton.

Pack sizes:
6, 7, 10 and 14 prolonged-release tablets.
Not all pack sizes may be marketed.

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