

Package leaflet: Information for the patient

KLACID® LA 500 mg Modified 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 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 Klacid LA is and what it is used for
2. What you need to know before you take Klacid LA
3. How to take Klacid LA
4. Possible side effects
5. How to store Klacid LA
6. Contents of the pack and other information

1. What Klacid LA is and what it is used for

Klacid LA is an antibiotic belonging to a group called the macrolides. Antibiotics stop the growth of certain germs that cause infections. Its use is described below. Klacid LA tablets are modified release tablets, which means that the active ingredient is released slowly from the tablet so that you only have to take the medicine once a day.

What are Klacid LA tablets used for?

The Klacid LA tablets are used to treat infections such as:

1. Chest infections such as bronchitis and pneumonia
2. Throat and sinus infections
3. Skin and soft tissue infections, which may also be called cellulitis, folliculitis or erysipelas.

Klacid LA Tablets are used in adults and children 12 years and older.

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

Do not take Klacid LA tablets

- If you know that you are allergic to clarithromycin or other antibiotics from the same drug class (macrolide antibiotics) such as erythromycin or azithromycin, or if you are allergic to any of the other ingredients of this medicine (listed in section 6).
- If you are taking ergot alkaloids (e.g. ergotamine or dihydroergotamine tablets) or use ergotamine inhalers for migraine, or oral midazolam (for anxiety or to help sleep).
- If you are taking other medicines which are known to cause serious disturbances in heart rhythm.
- If you are taking medicines called astemizole or terfenadine (medicine taken for hay fever or allergies), cisapride or domperidone (used for stomach disorders) or pimoziide (medicine used to treat certain psychiatric diseases), as taking these medicines with Klacid can cause serious disturbances in heart rhythm.
- If you are taking ticagrelor or ranolazine (medicine taken for angina or to reduce the chance of heart attack or stroke) .
- If you have abnormally low levels of potassium or magnesium in your blood (hypokalaemia or hypomagnesaemia).
- If you are taking drugs for high cholesterol (such as lovastatin or simvastatin).
- If you are taking a medicine containing lomitapide.
- If you have severe liver and/or severe kidney problems.
- If you had or currently have heart rhythm disorders (ventricular cardiac arrhythmia, including torsades de points) or abnormality of electrocardiogram (ECG, electrical recording of the heart) called "long QT syndrome".
- If you are taking colchicine (for gout).

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

Take special care with Klacid LA

- If you are pregnant or breast feeding (see Pregnancy and breast-feeding) .
- If you develop severe or prolonged diarrhoea during or after taking Klacid LA tablets, consult your doctor immediately.
- If you have certain heart problems (coronary artery disease, severe cardiac insufficiency, abnormal heart rhythms or clinically relevant slow heart rate).

- 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.

Taking other medicines

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.

Klacid must not be taken with ergot alkaloids, astemizole, terfenadine, cisapride, domperidone, pimoziide, 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 Klacid**).

In particular tell your doctor or pharmacist if you are taking any of the following medicines:

- digoxin, quinidine or disopyramide (heart drugs);
- warfarin, or any other anticoagulant e.g. dabigatran, rivaroxaban, apixaban (blood thinner);
- eletriptan (for migraine);
- carbamazepine, valproate, phenobarbital or phenytoin (for epilepsy or bipolar disorder (manic-depression));
- St. John's Wort (a herbal product used to treat depression);
- theophylline (for asthma or emphysema);
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- triazolam, alprazolam or intravenous or buccal (oromucosal) midazolam (for anxiety or to help sleep);
- omeprazole (for stomach disorders);
- quetiapine or ziprasidone (for schizophrenia or other psychiatric conditions);
- zidovudine, ritonavir, atazanavir, saquinavir, nevirapine, efavirenz or etravirine (for HIV);
- rifabutin, rifapentine or rifampicine (antibiotics effective against some infections such as tuberculosis);
- itraconazole or fluconazole (for fungal infections);
- sildenafil, tadalafil or vardenafil (for erectile dysfunction);
- tolterodine (for bladder problems);
- methylprednisolone (a steroid to treat inflammation);
- ibritinib or vinblastine (for cancer treatment);
- aprepitant (for preventing vomiting during chemotherapy);
- cilostazol (to improve circulation in the legs);
- any betalactam antibiotics (certain penicillins and cephalosporin antibiotics);
- tacrolimus, sirolimus or cyclosporin (to help organ transplants).
- nateglinide, repaglinide, sulphonylureas or insulin (medicines used to treat diabetes)
- aminoglycosides (medicines used as antibiotics to treat infections);
- calcium channel blockers (medicines to treat high blood pressure)

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, be sure to consult your doctor or pharmacist before taking Klacid LA. The safety of Klacid LA tablets in pregnancy and breast feeding is not known.

Driving and using machines

Klacid LA may cause dizziness. Therefore, it may affect your ability to drive or use machinery.

Important information about some of the ingredients of Klacid LA

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

This medicine contains 15.3 mg sodium (main component of cooking/table salt) in each tablet. If you receive two modified release tablets once daily, the resulting sodium amount in total is 30.6 mg per dose. This is equivalent to 1.5% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to take Klacid LA

Always take Klacid LA exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The usual dose of Klacid LA for adults and children over 12 years is 500 mg once daily for 6 to 14 days. Your doctor may increase the dose to two 500 mg tablets in severe infections. You should take both of these tablets at the same time. You may receive a pack with 2 tablets in each blister pocket in order to make it easier for you to do this.

You may be given a pack containing a single dose of Klacid LA so that you can start your treatment immediately. This one dose is not a full course of treatment. You should also receive a prescription for the rest of the tablets that you need.

Method or route of administration

Klacid 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.

Do not stop taking Klacid LA tablets because you feel better. It is important to take the tablets for as long as the doctor has told you to, otherwise the infection may not be completely treated and the problem may come back.

Use in children

These tablets may not be suitable for children under 12 years because they cannot be easily swallowed. Liquid medicines are therefore generally preferable for children. Your doctor will prescribe another suitable medicine for your child.

If you forget to take Klacid LA

If you forget to take a Klacid LA tablet, take one as soon as you remember. Do not take more tablets in one day than your doctor has told you to.

If you take more Klacid LA than you should

If you accidentally take more than two Klacid LA tablets in one day or if a child accidentally swallows some tablets, seek medical advice urgently, even if there are no symptoms or problems. An overdose of Klacid LA tablets is likely to cause vomiting and stomach pains and there is a possibility of allergic reactions.

4. Possible side effects

Like all medicines, Klacid LA can cause side effects, although not everybody gets them. If you suffer from any of the following side effects, stop taking your tablets and contact your 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 side effects

Common side effects of Klacid LA (may affect up to 1 in 10 people) are:

- Insomnia
- Headache
- Changes in the sense of taste (dysgeusia)
- Diarrhoea
- Vomiting
- Nausea
- Feeling or being sick
- Indigestion, abdominal pain
- Abnormal blood test (raised liver enzymes)
- Rash
- Increased sweating

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

- Infections such as infections of the stomach and intestine, inflammation of the skin caused by infections, oral or vaginal thrush and vaginal infections
- Low levels of white blood cells, and other white blood cell disorders
- Allergic reactions such as rashes, swelling, itching, hives
- Decreased appetite, loss of appetite
- Anxiety
- Nervousness
- Fainting, dizziness, tremors, drowsiness
- Ringing in the ears, vertigo (sensation of spinning) and ear disorders
- Lack of energy, chest pain, swelling of the face, a feeling of general discomfort, pain and thirst
- Changes in heart rhythm, electrocardiogram QT prolonged (abnormal findings in the electrocardiogram)
- Asthma and shortness of breath
- Nosebleed
- Constipation, rectal pain, dry mouth, excess gas in the stomach, burping, and flatulence (wind)
- Heartburn, gastritis (inflammation of gastric mucosa), stomatitis (inflammation of the mouth), glossitis (inflammation of the tongue)
- Muscle pain, muscle cramps
- Chills, tiredness, pyrexia

The following are side effects with an unknown frequency:

- Bacterial infection of the outer layers of the skin
- Psychiatric disorders such as abnormal dreams, being in a state of confusion, depersonalisation, disorientation, hallucination (seeing things), psychotic disorder, depression, mania
- Convulsions or fits, loss of taste, abnormal smell or loss of smell, pins and needles
- Deafness
- Ventricular fibrillation (uncoordinated contraction of the heart muscle)
- Bleeding
- Kidney disorders including inflammation of the kidney, and the presence of blood in the urine
- Acute pancreatitis (upper abdominal pain, going through to the back, which may be associated with loss of appetite, feeling or being sick)
- Tongue discolouration, tooth discolouration
- Acne
- Low blood counts (signs may include pale skin and tiredness) and low counts of certain blood elements that help fight infection (signs may include sore throat, fever, feeling very sick, easy bruising, bleeding)
- Muscle weakness

If you have a blood test while taking Klacid 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 Klacid 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 Klacid cannot treat, your symptoms may get worse. If this happens, be sure to consult your doctor.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 Klacid LA

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month. If the tablets are out of date, return them to your pharmacist and, if necessary, get a new prescription from your doctor.

Do not store your medicine above 30 °C. Keep the container in the outer carton in order to protect from light and moisture.

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

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 Klacid LA contains

The active substance is 500 mg of clarithromycin

The other ingredients are: citric acid, sodium alginate, sodium calcium alginate, povidone 40, talc, stearic acid 95%, magnesium stearate, hydroxypropyl methylcellulose, macrogol (400), macrogol (8000), titanium dioxide (E171), sorbic acid, quinoline yellow dye, aluminium lake and lactose monohydrate.

What Klacid LA looks like and contents of the pack

Yellow, ovaloid modified-release tablets. 7 tablets in a blister original pack. The blisters are packaged in a cardboard carton with a pack insert.

Product procured from within the EU, repackaged and distributed by the Parallel Product Authorisation holder:

PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland.

Parallel Product Authorisation Number

PPA 465/51/4

Manufacturer

Aesica Queenborough Ltd., Queenborough, Kent, United Kingdom or AbbVie S.r.l., Campoverde di Aprilia (LT), Italy.

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