

Package leaflet: information for the patient

Klacid XL Modified-Release Tablets 500mg

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 KLACID XL is and what it is used for
2. What you need to know before you take KLACID XL
3. How to take KLACID XL
4. Possible side effects
5. How to store KLACID XL
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1. What KLACID XL is and what it is used for

KLACID XL contains clarithromycin, an active substance belonging to a group of medicines called macrolide antibiotics. Antibiotics are medicines that block the growth of bacteria that cause infections.

KLACID XL is used to treat:

- respiratory tract infections such as bronchitis and pneumonia;
- throat infections (tonsillitis, pharyngitis) and paranasal sinus infections;
- skin and tissue infections, for example impetigo, folliculitis, erysipelas, furunculosis and infected wounds.

KLACID XL is a medicinal product in the form of modified-release tablets; this means that the active substance is slowly released from the tablet. This means that KLACID XL need only be taken once per day.

2. What you need to know before you take KLACID XL

Do not take KLACID XL:

- if you are allergic to clarithromycin, to other types of macrolide antibiotics, such as erythromycin or azithromycin, or to any of the other ingredients of this medicine (listed in section 6);
- if you are taking ergotamine or dihydroergotamine, medicines used to treat headaches. The combination of these medicines with KLACID could result in serious side effects. Ask your doctor to recommend alternative medicines;
- if you are taking a medicine containing lomitapide

- if you are taking astemizole or terfenadine (medicines widely used to treat hay fever or allergies) or cisapride or domperidone (medicines used to treat stomach disorders) or pimozide (medicine used to treat mental problems). The combination of these medicines with KLACID could result in severe heart rhythm disorders. Ask your doctor to recommend alternative medicines;
- if you are taking ticagrelor (medicine used to make your blood thinner), ivabradine or ranolazine (medicine used for heart disease). Ask your doctor to recommend alternative medicines;
- if you are taking midazolam (medicine used as an anaesthetic) or colchicine (medicine used to treat gout). The combination of these medicines with KLACID could result in serious side effects. Ask your doctor to recommend alternative medicines;
- If you are taking lovastatin or simvastatin (a type of statin), medicines used to lower blood cholesterol levels. The combination of these medicines with KLACID could result in severe muscle problems. Ask your doctor to recommend alternative medicines;
- if you have or have had the following heart problems: prolonged QT interval or cardiac ventricular arrhythmia;
- if you have low blood potassium or magnesium levels (hypokalaemia or hypomagnesaemia);
- if you have severe liver problems associated with kidney problems;
- if you have severe kidney problems.

KLACID XL is not suitable for children under 12 years of age.

Warnings and precautions

Talk to your doctor before taking KLACID XL if:

- you are elderly (over 65 years of age);
- you have liver or kidney problems;
- you have a fungal infection (e.g. thrush) or know you are at risk for this condition;
- you have a heart condition, for example severe heart failure or heart vessel problems (coronary heart disease);
- you have heart rhythm problems or a slow heart rate (bradycardia);
- you are taking other medicines that may cause ear damage (ototoxicity). In this case, your doctor could prescribe you exams to test vestibular and auditory functions;
- you are pregnant or breast-feeding.

Other medicines and KLACID XL

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including over-the-counter medicines.

KLACID must not be taken with ergot alkaloids, astemizole, terfenadine, cisapride, domperidone, pimozide, ticagrelor, ranolazine, colchicine, certain medicines for the treatment of high cholesterol and medicines known to cause severe heart rhythm disorders (the section "**Do not take KLACID**").

Do not take KLACID XL if you are also taking midazolam, a medicine used as an anaesthetic.

It is especially important that you tell your doctor if you are taking:

- medicines for heart problems, such as digoxin;
- heart rhythm medications (antiarrhythmics), such as quinidine, disopyramide;
- calcium channel blockers, such as verapamil, amlodipine and diltiazem, used to treat high blood pressure;
- oral blood-thinners (anticoagulants), such as warfarin, or any other anticoagulant, e.g. dabigatran, rivaroxaban, apixaban, edoxaban, cilostazol;
- epilepsy medicines (phenytoin, carbamazepine, phenobarbital, valproate);

- St. John's wort, used to treat depression or anxiety;
- medicines to treat HIV infection, such as efavirenz, etravirine, nevirapine, ritonavir, zidovudine;
- rifampicin, rifabutin and rifapentine, medicines used to treat bacterial infections;
- itraconazole and fluconazole, medicines used to treat fungal infections;
- zidovudine and saquinavir, antiviral medicines;
- Triazolobenzodiazepines, such as alprazolam, triazolam, medicines used to treat anxiety;
- atypical antipsychotics, such as quetiapine, medicines used to treat schizophrenia or other mental disorders;
- sirolimus, tacrolimus and ciclosporin, medicines used to weaken the immune system;
- medicines used to lower blood sugar levels (oral hypoglycaemic agents/insulin), such as nateglinide and repaglinide;
- other types of statin (other than lovastatin or simvastatin), medicines used to lower blood cholesterol levels;
- omeprazole, a medicine used for certain stomach disorders such as ulcers;
- theophylline, a medicine used to treat respiratory diseases;
- methylprednisolone, a cortisone;
- ibrutinib or vinblastine, medicines used to treat cancer;
- tolterodine, a medicine used to treat urinary incontinence;
- medicines that cause a change in the electrocardiogram called long QT syndrome or torsade de pointes;
- ergot alkaloids, used, for example, to treat headaches;
- medicines for impotence, such as sildenafil, tadalafil and vardenafil.
- 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)

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 for advice before taking this medicine because the safety of KLACID XL during pregnancy and breast-feeding is not known.

Driving and using machines

KLACID XL may cause dizziness, vertigo, confusion and disorientation. Ensure that you are not suffering from such side effects before driving or operating machines.

KLACID XL contains:

- **lactose.** If you have been diagnosed with an intolerance to some sugars, speak to your doctor before taking this medicine;
- **sodium.** This medicine contains 15.3 mg of sodium (the main component of table salt) in each tablet. If you take two modified-release tablets once a day, the total amount of sodium is 30.6 mg per dose. This is equal to 1.5% the recommended maximum daily intake of sodium for adults.

3. How to take KLACID XL

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

The recommended KLACID XL dose for adults and adolescents over 12 years of age is 1 tablet once per day for 5-14 days.

For severe infections, the doctor may increase the dose to 2 tablets per day to be taken at the same time.

Method of administration

KLACID XL must be taken by mouth (oral use) and with food. The tablet must be swallowed whole without chewing.

Patients with severe kidney problems

KLACID XL is not suitable for patients with severe kidney problems (creatinine clearance lower than 30 ml/min). Ask your doctor if necessary, as there are other available dosages (smaller) available specifically for these patients.

Children

KLACID XL is not recommended for children under 12 years of age. In this case, use KLACID 125 mg/5 mL granules for oral suspension or KLACID 250 mg/5 mL granules for oral suspension in a bottle with a spoon or dosing syringe.

If you take more KLACID XL than you should, you could experience stomach or intestinal problems. If you take high doses of KLACID XL, or if a child accidentally swallows some tablets, call your doctor immediately or go to the nearest hospital.

If you forget to take KLACID XL

If you forget to take the dose of medicine at the correct time, take it as soon as possible. However, if it is almost time for your next dose, skip the dose you forgot. Do not take a double dose to make up for a forgotten dose.

If you stop taking KLACID XL

It is important that you take this medicine for as long as prescribed by the doctor. Do not stop the treatment just because you feel better as your symptoms may manifest again or worsen.

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.

Stop taking KLACID XL immediately and see your doctor if you have any of the following conditions:

- severe allergic reactions: swelling (angioedema) of the face, eyes, lips, tongue and throat, difficulty breathing, increased heart rate with possible sudden drop in blood pressure (anaphylactic reactions);
- severe skin rashes with redness, blistering and peeling, mouth, lip and skin ulcerations (Stevens-Johnson syndrome, toxic epidermal necrolysis);

- skin rash with fever and blood, lung, heart or liver abnormalities (DRESS syndrome);
- weight loss, yellowing of the eyes or skin (jaundice), dark urine, pale stools, itching or abdominal pain (possible signs of liver failure);
- severe or persistent diarrhoea, presence of blood in the diarrheal stool, even up to 2 months after the last dose (possible signs of pseudomembranous colitis caused by a bacterium called *Clostridioides difficile*).

Contact your doctor immediately if you notice a severe skin reaction: red and scaly skin rash with pustules and vesicles (exanthematous pustulosis). The frequency of this reaction is not known (cannot be estimated from the available data).

Contact your doctor if the following appear during treatment with KLACID XL:

Common side effects (may affect up to 1 in 10 people)

- difficulty falling asleep (insomnia);
- taste changed, headache;
- diarrhoea, vomiting, nausea, indigestion, abdominal pain;
- abnormal liver function tests;
- excessive sweating;
- skin rash.

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

- Candida infections, vaginal infections;
- decrease in the number of white blood cells (which can make infections more likely);
- anorexia, decreased appetite;
- anxiety, dizziness, vertigo, drowsiness, tremor;
- ringing in the ear, impaired hearing;
- electrocardiogram abnormalities (prolonged QT interval), feeling of "heart in the throat";
- mouth or tongue inflammation, dry mouth, stomach inflammation (gastritis), difficulty in passing stools (constipation), belching, gas in the intestine (flatulence);
- itching (pruritus), hives (urticaria);
- feeling weak (asthenia);
- abnormal blood tests: increased transaminases (alanine aminotransferase and aspartate aminotransferase).

Additional side effects

- skin infection (erysipelas);
- decrease in blood platelet levels (with increased risk of bruising or bleeding);
- decreased number of a certain type of white blood cell called granulocytes (agranulocytosis);
- changes in the perception of sense of reality (psychotic disorder) or of oneself (depersonalisation), confusion, depression, disorientation, hallucinations (seeing things that are not real), abnormal dreams, manias, convulsions, smell alterations (ageusia, parosmia, anosmia), numbness or a "tingling" sensation (paraesthesia);
- loss of hearing;
- heart rhythm disorders (torsade de pointes, ventricular tachycardia, ventricular fibrillation);
- bleeding;
- inflammation of the pancreas;
- tongue or teeth colour changes;
- acne;

- muscle disorders (myopathy) such as loss of muscle tissue (rhabdomyolysis);
- abnormal urine colour, kidney problems such as inflammation or insufficiency;
- abnormal laboratory tests such as: increased international normalised ratio, prolonged prothrombin time.

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 ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store KLACID XL

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 pack. The expiry date refers to the last day of that month.

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 XL contains

The active substance is clarithromycin.

Each modified-release tablet contains: 500 mg of clarithromycin.

The other ingredients are: anhydrous citric acid, **sodium** alginate, **sodium** and calcium alginate, **lactose**, povidone K30, talc, stearic acid, magnesium stearate, hypromellose, macrogol 400, macrogol 8000, titanium dioxide, sorbic acid, quinoline yellow (E104 aluminium lacquer).

What KLACID XL looks like and contents of the pack

This medicinal product is available in packs of 5,6,7,14,16 or 20 tablets modified-release tablets.

Marketing Authorisation Holder

Viatris Healthcare Limited
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Manufacturer

AbbVie S.r.l. - Campoverde di Aprilia (LT)

If you have further questions about this medicine, please contact the local representative of the marketing authorisation holder.

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