

PACKAGE LEAFLET: INFORMATION FOR THE USER

Klariger 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 on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any of the 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 Klariger LA is and what it is used for
2. What you need to know before you take Klariger LA
3. How to take Klariger LA
4. Possible side effects
5. How to store Klariger LA
6. Contents of the pack and other information

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

Klariger LA is an antibiotic belonging to a group of medicines called the macrolides. Antibiotics stop the growth of bacteria (bugs), which cause infections.

Klariger 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 it once a day.

Klariger LA is indicated in adults and children 12 years and older.

Klariger LA is used to treat infections such as:

- Chest infections such as bronchitis and pneumonia
- Throat and sinus infections
- Mild to moderate skin and tissue infections, such as folliculitis, cellulitis or erysipelas.

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

Do not take Klariger LA if you:

- If you are allergic (hypersensitive) to clarithromycin, other macrolide antibiotics such as erythromycin or azithromycin, or any of the other ingredients in the tablets (listed in section 6).
- Have a creatinine clearance of less than 30ml/min.
- have an irregular heart rhythm.
- Suffer from severe kidney and liver problems.
- are taking medicines called ergotamine or dihydroergotamine tablets or use ergotamine inhalers for migraine while taking Klariger LA tablets. Consult your doctor for advice on alternative medicines.
- are taking medicines called terfenadine, or astemizole (widely taken for hay fever or allergies) or cisapride (for stomach problems) or pimozone (for mental problems) while taking Klariger LA tablets, as combining these drugs can sometimes cause serious disturbances in heart rhythm. Consult your doctor for advice on alternative medicines.
- Are taking medicines called lovastatin or simvastatin (to lower cholesterol levels), as combining these drugs can sometimes increase the possibility of side effects. Consult your doctor for advice on alternative medicines.

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine if:

- you have any heart, kidney or liver problems
- you have, or are prone to, fungal infections (e.g. thrush)
- you are pregnant or breast feeding.
- you are taking medicines called colchicines, triazolam, midazolam, lovastatin, simvastatin.
- you are diabetic, (your glucose levels will need to be monitored).
- you are taking a medicine called warfarin (to thin your blood).
- you have myasthenia gravis, a condition in which your muscles become weak and tire easily
- you develop severe or prolonged diarrhoea during or after taking Klariger LA, consult your doctor immediately.

If any of these apply to you, consult your doctor before taking Klariger LA tablets.

Children and adolescents

Do not give this medicine to children below the age of 12 years.

Other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including those obtained without a prescription. This is especially important if you are taking medicines for;

- Heart problems (e.g. digoxin, verapamil, quinidine or disopyramide).
- Thinning your blood (e.g. warfarin)
- Migraines (e.g. ergotamine or dihydroergotamine)
- Epilepsy (carbamazepine, valproate or phenytoin)
- High cholesterol (e.g. simvastatin or lovastatin)

or if you are taking any medicines called:

- Colchicine (usually taken for gout)
- Theophylline (used in patients with breathing difficulties such as asthma)
- Terfenadine or astemizole (for hay fever or allergy)
- Triazolam, alprazolam or midazolam (sedatives)
- Cilostazol (for poor circulation)
- Cisapride (for stomach disorders)
- Methylprednisolone (a corticosteroid)
- Vinblastine (for treatment of cancer)
- Ciclosporin (immune suppressant)
- Pimozide (for mental problems)
- Rifabutin (for treatment of some infections)
- Tacrolimus (for organ transplants and severe eczema)
- Sildenafil, tadalafil or vardenafil (for impotence in adult males or for use in pulmonary arterial hypertension (high blood pressure in the blood vessels of the lung))
- Zidovudine (to treat viruses)
- St John's Wort (herbal product to treat depression.
- Phenobarbital (drug for epilepsy).
- Nevirapine & Efavirenz may lower the levels of Klariger LA.
- Rifampicin (to treat tuberculosis)
- Omeprazole (to treat heart burn & stomach/intestinal ulcers)
- Ritonavir (anti-viral drug used in the treatment of HIV infection) may increase the levels of Klariger LA. Atazanavir & Saquinavir (also anti-viral drugs used in the treatment of HIV

infection): Taking these drugs with Klariger LA may increase both the levels of Atazanavir (or Saquinavir) and Klariger LA.

- Itraconazole (an anti-fungal drug) taken together with Klariger LA may increase the levels of both medicines.
- Fluconazole, another anti-fungal drug, may increase the levels of Klariger LA.
- Tolterodine (to treat symptoms of overactive bladder syndrome). In certain patients, the levels of tolterodine may be increased when taken with Klariger LA.

Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant, or if you are breast-feeding, consult your doctor before taking Klariger LA tablets, as the safety of Klariger LA tablets in pregnancy and breast-feeding is not known.

Driving and using machines

Do not drive or operate machinery if you feel dizzy, drowsy or confused while taking this medicine.

Klariger LA contains lactose monohydrate

This medicine product contains lactose monohydrate. 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 Klariger LA

Do not give these tablet to children under 12 years. Your doctor will prescribe another suitable medicine for your child.

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

Patients with severe kidney and liver problems:

Patients with severe kidney and liver problems should not take Klariger LA.

The recommended dose of Klariger LA tablets for adults and children 12 years and older is one 500 mg tablet once a day for 6 to 14 days.

Your doctor may increase the dose to two 500 mg tablets daily in severe infections.

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

If you take more Klariger LA than you should

If you accidentally take more Klariger LA 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 Klariger LA tablets is likely to cause vomiting and stomach pains.

If you forget to take Klariger LA

If you forget to take a dose of Klariger LA tablets, take it as soon as you remember. Do not take more tablets in one day than your doctor has told you to. Do not stop taking Klariger LA 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.

Stop taking Klariger LA and seek medical help immediately if you have any of the following allergic reactions:

-If you develop severe or prolonged diarrhoea, which may have blood or mucus in it, during or after taking Klariger LA tablets, consult your doctor immediately.

-If you develop 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.

Other possible side effects include:

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

- Insomnia (difficulty falling asleep)
- Headache
- Rash
- Feeling sick (nausea) & vomiting
- Indigestion (upset stomach)
- Heartburn
- Abdominal (stomach) pain
- Diarrhoea
- Vasodilation
- Change in the sense of taste
- Abnormal liver function test results

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

- Inflammation of the stomach and intestine, oral thrush, rash, inflammation of the nose causing it to run, vaginal thrush and vaginal infections
- Low levels of white blood cells, anaemia, other white blood cell disorders and an excessive level of platelets in the blood (blood cells that help you stop bleeding) leading to abnormal blood clotting or bleeding
- Anorexia, decreased appetite
- Psychiatric disorders such as anxiety
- Dizziness, and tremor
- Ringing in the ears, vertigo and ear disorders
- Palpitations (a fast heart beat)
- Shortness of breath and other lung disorders
- Bloating (excess gas in the stomach), constipation, dry mouth, burping, passing gas, bleeding from the stomach, inflammation of the corners of the mouth, tongue discolouration, vomiting and other stomach and intestine disorders
- Yellowing of the skin and eyes (jaundice)
- Dry skin, eczema, itching of the skin, rash, hives, and excessive perspiration
- Back and muscle pain
- Kidney disorders including the presence of protein and blood in urine, passing urine with pus (if you have a urine test)
- Lack of energy, chest pain, swelling of face, a feeling of general discomfort, pain and thirst
- If you have a blood test while taking Klariger LA, it may show raised liver enzymes and abnormal liver function test results. The presence of protein in the urine and other abnormalities may show the presence of kidney disorders. A decrease in clotting factor and an increase in other enzymes may also be detected.

Not known (frequency cannot be estimated from the available data):

- Decrease in platelets (blood cells that help you stop bleeding)
- Psychiatric disorders such as abnormal dreams, anxiety, confusional state, depersonalisation, disorientation, hallucination (seeing things) and other psychotic disorders
- Convulsions and change in the sense of smell
- Deafness
- Inflammation of the tongue and tooth discolouration
- Liver failure, abnormal liver function or hepatitis
- Acne
- Severe muscle pain
- Inflammation of the kidneys and
- Abnormal urine colour.

Inflammation of the colon (Pseudomembranous colitis) has been reported with nearly all antibacterial medicines including clarithromycin. Its symptoms include diarrhoea after taking clarithromycin. Please inform your doctor immediately if you suffer from diarrhoea.

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:

IMB Pharmacovigilance,
Earlsfort Terrace,
IRL- Dublin 2,
Ireland.
Tel: +353 1 6764971,
Fax: +353 1 6762517,
Website: www.imb.ie,
e-mail: imbpharmacovigilance@imb.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Klariger LA

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 carton 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 Klariger LA contains**

- Each tablet contains 500mg of clarithromycin as clarithromycin citrate.
- The active substance is clarithromycin.
- The other ingredients are lactose monohydrate, hypromellose, hypromellose phthalate, talc, magnesium stearate (E 572). The coating (Opadry II Yellow) contains hypromellose 15cP,

lactose monohydrate, titanium dioxide (E171), macrogol/PEG 4000, Talc (E553b); quinoline yellow aluminium lake (E104); macrogol/PEG 400.

What Klariger LA looks like and contents of the pack

Your medicine comes as a yellow coloured, oblong shaped, biconvex film-coated tablet of length $19.15 \pm 0.2\text{mm}$, width $8.95 \pm 0.2\text{mm}$ and thickness $7.55 \pm 0.2\text{mm}$ with both sides plain

Klariger LA is available in blisters of 5, 6, 7, 8, 10, 14, 16, 20, 21, 28, 30, 60 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

McDermott Laboratories Ltd t/a Gerard Laboratories
35/36 Baldoyle Industrial Estate
Grange Road
Dublin 13
Ireland

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	Clarithromycin Arcana 500 mg - Retardtabletten
Belgium	Clarithromycine Uno Mylan 500 mg tabletten met gereguleerde afgifte
Bulgaria	Clarithrogen 500 mg XR
Czech Republic	Klaritromycin Retard Mylan 500 mg, tablety s řízeným uvolnováním
Denmark	Klaritromyl
Finland	Klaritromyl
Hungary	Klarigen UNO
Ireland	Klariger LA 500 mg Modified-release tablets
Italy	Clarithromicina Mylan Generics Italia
Netherlands	Clarithromycine Retard Mylan 500 mg, tabletten met gereguleerde afgifte
Norway	Clarithromycin Mylan
Poland	Klarytrogen MR
Portugal	Clarithromicina Mylan
Romania	Clarithromicina Mylan 500 mg comprimate cu eliberare modificata
Slovakia	Klaritromycin Retard Mylan 500mg tablety s riadeným uvolnovaním
Spain	Clarithromicina Unidia Mylan 500 mg comprimidos de liberación modificada EFG
United Kingdom	Baktroquell XL Modified-release Tablets

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