

## **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 sign 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
2. What you need to know before you take Klaram LA
3. How to take Klaram LA
4. Possible side effects
5. How to store Klaram LA
6. Contents of the pack and other information

#### **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 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 any of the following consult your doctor for advice on alternative medicines:
  - ergotamine or dihydroergotamine tablets (for migraines).
  - lovastatin or simvastatin (for high cholesterol).
  - ticagrelor (a blood thinning medicine)

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- ranolazine (to treat angina)
- colchicine (for gout)
- cisapride (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 have kidney problems.
- 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 torsades de pointes) or abnormality of electrocardiogram (ECG, electrical recording of the heart) called “long QT syndrome”
- if you have severe liver problems in combination with kidney problems.

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Klaram LA

- if you are pregnant
- if you have liver problems
- if you develop severe or prolonged diarrhoea during or after taking Klaram LA, consult your doctor immediately
- if you are taking triazolam and midazolam (sedatives)
- if you are taking other ototoxic medicinal products, especially aminoglycosides (group of medicine to treat some infections)
- if you have coronary heart disease, severe cardiac insufficiency, slow heart beat (bradycardia)
- if you have repeated infections with bacteria or fungi. Consult your doctor for advice
- if you are taking atorvastatin or rosuvastatin (for high cholesterol)
- if you are taking certain anti-diabetic drugs (e.g. nateglinide, pioglitazone, repaglinide and rosiglitazone) as Klaram LA may lower your blood sugar levels
- if you are taking anticoagulants (medicines to thin the blood).

In the event of severe acute hypersensitivity reactions, such as anaphylaxis, Stevens-Johnson Syndrome, and toxic epidermal necrolysis, Klaram LA therapy should be discontinued immediately and appropriate treatment should be urgently initiated.

### **Other medicines and Klaram LA**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. You should not take Klaram LA if you are taking any of the medicines listed in the section above “Do not take Klaram LA”

Consult your doctor 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, diltiazem (heart drugs);
- carbamazepine, valproate, phenobarbital or phenytoin (drugs for epilepsy);

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- statins for high cholesterol (such as atorvastatin, rosuvastatin);
- warfarin (blood thinner);
- quetiapine (antipsychotic)
- sildenafil, tadalafil or vardenafil (for treating erectile dysfunction);
- theophylline (helps breathing);
- tolterodine (to treat symptoms of overactive bladder syndrome);
- triazolam, alprazolam or midazolam (sedatives);
- omeprazole (for stomach disorders);
- tacrolimus, sirolimus or cyclosporin (for organ transplants);
- methylprednisolone (a corticosteroid to treat inflammation);
- vinblastine (a chemotherapy agent used to treat cancer);
- cilostazol (used to improve circulation in the legs);
- St John's Wort (herbal remedy);
- verapamil;
- insulin or oral anti-diabetic medicines such as nateglinide or repaglinide (to reduce blood sugar levels).

### **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**

There are no data on the effect of clarithromycin on the ability to drive or use 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.

Adults and children over 12 years

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.

Children 12 years old and younger:

These tablets are not suitable for children 12 years old and younger. 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 pain in the abdomen and back caused by inflammation of the pancreas. This effect is of unknown frequency.
- Dark urine, pale stools, jaundice (yellowing of the skin and/or eyes), nausea and fever which can be symptoms of liver problems. This effect is of unknown frequency.
- Sudden wheezing, swelling of your lips, face or body, rash, fainting or difficulties swallowing (severe allergic reaction). This effect is of unknown frequency.
- Severe and painful diarrhoea caused by inflammation of the intestines (pseudomembranous colitis). This effect is of unknown frequency.
- Reddening of the skin with blisters or peeling and may be associated with a high fever and joint pain. There may also be severe blisters and bleeding in the lips, eyes, mouth, nose and genitals.

This could be Stevens-Johnson syndrome or toxic epidermal necrolysis. This effect is of unknown frequency.

### **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 or loss of sense of taste (dysgeusia), headache.
- Dilation of a blood vessel<sup>1</sup>.
- 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<sup>2</sup>, infections<sup>3</sup>, vaginal infections, inflammation of the skin caused by infections<sup>1</sup>.
- Change in the numbers of blood platelets (thrombocytopenia), neutrophils (neutropenia)<sup>4</sup>, or white blood cells (leukopenia).
- Increased number of white blood cells called eosinophils (eosinophilia)<sup>4</sup>.
- Anaphylactoid reaction<sup>1</sup>, hypersensitivity.
- Anorexia, decreased appetite.
- Anxiety, nervousness<sup>3</sup>.
- Loss of consciousness<sup>1</sup>, difficulty controlling movement<sup>1</sup>, dizziness, sleepiness and tremor.
- Ringing in the ears (tinnitus), sensation of spinning or whirling motion (vertigo) and hearing impairment.
- Heart stops beating (cardiac arrest)<sup>1</sup>, irregular heart and pulse rate<sup>1</sup>, abnormal electric activity tracing of the heart (ECG), aware of heart beat (palpitation), premature heart beat (extrasystoles)<sup>1</sup>.
- Asthma<sup>1</sup>, nosebleed<sup>2</sup>, obstruction of pulmonary arteries<sup>1</sup>.
- Inflammation of the oesophagus<sup>1</sup>, heartburn<sup>2</sup>, inflammation of the stomach, pain in the rectum (proctalgia)<sup>2</sup>, inflammation of the inside of the mouth (stomatitis), inflammation of the tongue (glossitis), constipation, swollen stomach (abdominal distension), burping (eructation), dry mouth, flatulence.
- Failure in the flow of bile (cholestasis)<sup>4</sup>, inflammation of the liver (hepatitis)<sup>4</sup>, increases in some liver enzymes (alanine and aspartate aminotransferase gamma-glutamyltransferase<sup>4</sup>).
- Inflammation of the skin with blisters (dermatitis bullous)<sup>1</sup>, 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)<sup>3</sup>.
- Muscle spasms<sup>3</sup>, muscle pain<sup>2</sup>, musculoskeletal stiffness<sup>1</sup>.
- Lack of energy<sup>4</sup>, weakness or loss of strength, fever<sup>3</sup>, chest pain<sup>4</sup>, chills<sup>4</sup>, mental or physical tiredness<sup>4</sup>.
- Increase of creatinine and urea in the blood<sup>1</sup>.
- Change in some blood tests (increase of alkaline phosphatase<sup>4</sup> and lactate dehydrogenase<sup>4</sup>), albumin globulin ratio abnormal<sup>1</sup>.

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

- Inflammation of the intestines causing severe and painful diarrhoea, bacterial skin infections (erysipelas).
- 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).
- 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, tooth discolouration.
- Liver failure, jaundice.
- 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)<sup>2</sup>.
- Kidney failure, inflammation of the kidneys (interstitial nephritis).
- Abnormal colour of the urine.
- Blood clotting time increased (increased INR and prothrombin time).
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<sup>1</sup> side effects reported only for the Powder for Solution for Injection formulation

<sup>2</sup> side effects reported only for the Extended-Release Tablets formulation

<sup>3</sup> side effects reported only for the Granules for Oral Suspension formulation

<sup>4</sup> side effects reported only for the Immediate-Release Tablets formulation

### 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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971, Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@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.

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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,  $19.15 \pm 0.2$ mm long,  $8.95 \pm 0.2$ mm width and  $7.55 \pm 0.2$ mm 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.

### Marketing Authorisation Holder

Actavis Group PTC ehf.  
Reykjavíkurvegi 76-78,  
220 Hafnarfjörður,  
Iceland

### Manufacturer

Balkanpharma-Dupnitsa AD  
3 Smokovsko Shosse Str.,  
2600 Dupnitsa  
Bulgaria

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

Austria	Clarithromycin Actavis 500 mg Retardtabletten
Denmark	Clarithromycin Actavis 500 mg depottabletter
Estonia	Clarithromycin Actavis

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Hungary	KLARILID 500 mg retard tabletta
Ireland	Klaram LA 500 mg Prolonged release Tablets
Lithuania	Clarithromycin Actavis 500 mg pailginto atpalaidavimo tabletės
Latvia	Clarithromycin Actavis 500 mg ilgstošās darbības tablets
Netherlands	Claritromycine Aurobindo SR 500 mg tabletten met verlengde afgifte
Portugal	Claritromicina Aurovitas
Romania	CLAXIRIT 500 mg comprimate cu eliberare prelungită
United Kingdom	Febzin XL 500 mg Prolonged-release Tablets

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