

PACKAGE LEAFLET

Package leaflet: Information for the user

Minatev 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 Minatev LA is and what it is used for
2. What you need to know before you take Minatev LA
3. How to take Minatev LA
4. Possible side effects
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1. What Minatev LA is and what it is used for

Minatev 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.

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

Minatev LA is used to treat the following infections:

- Bronchitis and pneumonia
- Throat and sinus infections
- Mild to moderate skin and soft tissue infections

Minatev LA is not suitable for children younger than 12 years of age. Your doctor may prescribe another form of clarithromycin.

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

Do not take Minatev LA

- if you are allergic to Clarithromycin, any other macrolide antibiotics (e.g. erythromycin, azithromycin) or any of the other ingredients of this medicine (listed in section 6).
- if you are taking medicines called terfenadine or astemizole (for hay fever or allergies) or cisapride (for stomach disorders) or pimozide (for mental illness) tablets as combining these drugs can sometimes cause serious disturbances in heart rhythm. Consult your doctor for advice on alternative medicines.
- 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 kidney problems. Your doctor may prescribe another form of clarithromycin.
- if you are taking ticagrelor (a blood-thinning drug)
- if you are taking ranolazine (used to treat angina)
- if you are taking ergotamine-like drugs (usually used for migraine)

- if you are taking simvastatin or lovastatin (to reduce cholesterol)
- if you have been told by your doctor that you have low levels of potassium in your blood (hypokalaemia)
- if you have severe liver disease with kidney disease
- if you are taking colchicine (used to treat gout)

Warnings and precautions

Talk to your doctor or pharmacist before taking Minatev LA if:

- you have any kidney or liver problems
- 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 Minatev LA, consult your doctor immediately.
- you have, or are prone to, bacterial infections or fungal infections (e.g. thrush)
- you are allergic to lincomycin or clindamycin (antibiotics).
- you have abnormally low levels of magnesium in your blood (hypomagnesaemia).
- you are taking other medicines which are known to cause serious disturbances in heart rhythm (for the medicines terfenadine, astemizole, cisapride, and pimozide: see ‘Do not take Minatev LA’).

Other medicines and Minatev LA

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

If taken with Minatev LA, the levels and therefore the effects of the following listed medicines may be increased:

- Digoxin, quinidine or disopyramide (heart drugs)
- Warfarin (blood thinner)
- Carbamazepine, valproate or phenytoin (drugs for epilepsy)
- Theophylline (for asthma)
- Triazolam, alprazolam or midazolam (sedatives)
- Omeprazole (for stomach disorders)

Minatev LA may interact with the Anti-viral [HIV] drugs in the following manner:

- Zidovudine, Minatev LA may lower the levels of zidovudine
- Ritonavir may increase the levels of Minatev LA
- Atazanavir & Saquinavir: Taking these drugs with Minatev LA may increase both the levels of Atazanavir (or Saquinavir) and Minatev LA
- Nevirapine & Efavirenz may lower the levels of Minatev LA
- Etravirine may lower the levels of Minatev LA

Other interactions include:

- Rifabutin (an antibiotic effective against some infections) may lower the levels of Minatev LA.
- Itraconazole (an anti-fungal drug) taken together with Minatev LA may increase the levels of both medicines.
- Fluconazole, another anti-fungal drug, may increase the levels of Minatev LA.
- Sildenafil, tadalafil or vardenafil (for treating erectile dysfunction). Taking these drugs with Minatev LA may increase both their levels.
- Tolterodine (to treat symptoms of overactive bladder syndrome). In certain patients, the levels of tolterodine may be increased when taken with Minatev LA.
- Methylprednisolone (a corticosteroid to treat inflammation).
- Vinblastine (a chemotherapy agent used to treat cancer).
- Ziprasidone (an antipsychotic drug)
- Quetiapine (an atypical antipsychotic)
- Eletriptan (used for migraine).

- Halofantrine (used to treat malaria)
- Aprepitant (used to prevent vomiting during chemotherapy)
- Cilostazol (used to improve circulation in the legs)
- Rifampicin, rifapentine (to treat tuberculosis)
- Tacrolimus, sirolimus or cyclosporin (for organ transplants)
- St John's Wort (herbal product to treat depression.
- Phenobarbital (drug for epilepsy).
- Medicines used to treat diabetes, e.g. insulin, nateglinide, repaglinide
- Atorvastatin, rosuvastatin (HMG-CoA reductase inhibitors, commonly known as statins, and used to lower levels of cholesterol (a type of fat) in the blood)
- Aminoglycosides (antibiotics) e.g. gentamicin
- Calcium channel blockers e.g. verapamil, amlodipine, diltiazem (used to treat high blood pressure)

Minatev LA with food and drink

This medicine should be taken with food.

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.

Use of clarithromycin is not advised to pregnant or breast-feeding mothers unless the benefits to the mother outweigh the risks to the baby.

Clarithromycin is excreted into human breast milk

Driving and using machines

There are no data available on the effect of clarithromycin on the ability to drive or use machines. Your tablets may cause dizziness, confusion and disorientation. DO NOT drive or operate machinery if you are affected.

Minatev LA contains lactose

This medicine product 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 Minatev LA

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Your doctor will tell you how to take Minatev LA and how long for. Do not stop taking Minatev LA early even if your symptoms improve. It is important to take the tablets for as long as the doctor has told you to, otherwise the infection might come back.

- The tablets should be swallowed whole with some liquid
- The tablets should not be chewed or halved
- The tablets should be taken once daily preferably at the same time each day for your course of treatment
- The tablets should be taken with food

Dosage

The recommended dose is:

Adults including the elderly and children 12 years and older: The recommended dose is 500 mg once daily for 6 days to 14 days. However your doctor will decide the length of your treatment. 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.

Children under 12 years: Do not give this medicine to children under 12 years of age. Your doctor will prescribe another suitable medicine for your child.

Patients with severe kidney and liver problems:

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

If you take more Minatev LA than you should

Contact your doctor or nearest hospital emergency department **immediately**. Take the container and any remaining tablets with you. Symptoms of overdose include feeling or being sick, diarrhoea, indigestion or stomach pains and there is the possibility of allergic reactions.

If you forget to take Minatev LA

Take the next dose as soon as you remember unless it is almost time for your next dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Minatev LA

Do not stop taking Minatev 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 suffer from any of the following at any time during your treatment STOP TAKING your tablets and contact your doctor immediately. These side effects are of unknown frequency:

- severe or prolonged diarrhoea, which may have blood or mucus in it. Diarrhoea may occur over two months after treatment with clarithromycin, in which case you should still contact your doctor.
- a rash, difficulty breathing, fainting or swelling of the face and throat. This is a sign that you may have developed an allergic reaction.
- yellowing of the skin (jaundice), skin irritation, pale stools, dark urine, tender abdomen or loss of appetite. These may be signs that your liver may not be working properly.
- severe skin reactions such as blistering of the skin, mouth, lips, eyes and genitals (symptoms of a rare allergic reaction called Stevens-Johnson syndrome/toxic epidermal necrolysis).
- torsade de pointes, a life threatening irregular heart beat.

Contact a doctor immediately if you experience a serious skin reaction: a red, scaly rash with bumps under the skin and blisters (exanthematous pustulosis). The frequency of this side effect is not known (cannot be estimated from the available data).

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

- headache
- difficulty sleeping
- changes in sense of taste
- stomach problems such as feeling sick, vomiting, stomach pain, indigestion, diarrhoea
- abnormal liver function (seen in blood results)
- skin rash
- increased sweating

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

- oral or vaginal 'thrush' (a fungal infection)
- reduction in the level of certain blood cells (which can make infections more likely)

- loss of appetite, heartburn, constipation, wind, burping (eructation)
- anxiety, nervousness, drowsiness, tiredness, weakness, dizziness, tremor or shaking, or a general feeling of being unwell
- ringing in the ears or hearing loss
- vertigo
- inflammation of the mouth or tongue
- inflammation of the stomach, pain in the rectum (proctalgia)
- dry mouth
- muscle pain
- chest pain or changes in heart rhythm such as palpitations
- nosebleed
- failure in the flow of bile (cholestasis), a change in the levels of products made by the liver, inflammation of the liver, an inability of the liver to function properly or liver failure (you may notice yellowing of the skin, dark urine, pale stools or itchiness of the skin)
- itching of the skin, hives

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

- swelling, redness or itchiness of the skin (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)
- swelling of the lips and face (angioedema)
- drug rash with eosinophilia and systemic symptoms (DRESS)
- acne
- inflammation of the pancreas
- confusion, loss of bearings, hallucinations (seeing things), change in sense of reality or panicking, depression, abnormal dreams or nightmares, mania
- convulsion (fits)
- bleeding
- discolouration of the tongue or teeth
- loss of taste or smell or inability to smell properly
- pins and needles
- deafness
- muscle pain or loss of muscle tissue. If you suffer from myasthenia gravis (a condition in which the muscles become weak and tire easily) clarithromycin may worsen these symptoms
- low blood sugar levels
- inflammation of the kidney or an inability of the kidney to function properly (you may notice tiredness, swelling or puffiness in the face, abdomen, thighs or ankles or problems with urination), or kidney failure
- abnormal colour of the urine
- blood clotting time increased

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; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Minatev LA

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

PVC/PVdC aluminium blister pack

Do not store above 30°C.

Store in the original package in order to protect from moisture.

OPA/AL/PVC/AL blister pack

This product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the label after Exp. 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 to protect the environment.

6. Contents of the pack and other information

What Minatev LA contains

- The active substance is clarithromycin. Each tablet contains 500 mg clarithromycin.
- The other ingredients are: citric acid anhydrous, sodium calcium alginate, sodium alginate manucol, lactose monohydrate, povidone, talc, stearic acid, magnesium stearate, vanillin, opadry II 31F32870 Yellow (containing Lactose monohydrate, hypromellose (E464), titanium dioxide (E171), polyethylene glycol, iron oxide yellow (E172), iron oxide red (E172), iron oxide black (E172)).

What Minatev LA looks like and contents of the pack

Minatev LA Prolonged-release Tablets are light yellow to yellow, film-coated, oval shaped tablets debossed with “C” on one side and “500” on the other side.

Your tablets come in blister packs in pack sizes of 5, 6, 7, 10, 14, 20 & 1 tablet unit dose pack.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder

Teva Pharma B.V.
Swensweg 5
2031GA Haarlem
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Manufacturers

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Ludwig-Merckle-Strasse 3
89143 Blaubeuren
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This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	Clarithromycin ratiopharm 500 mg Retardtabletten
Belgium	Clarithromycine UNO Teva 500 mg tabletten met verlengde afgifte
Bulgaria	Kaplon XL 500 mg prolonged release tablets
Estonia	Klatex
Hungary	Clarithromycin-Teva 500 mg retard tabletta
Ireland	Minatev LA Prolonged-release Tablets
Italy	Claritromicina Teva Italia 500 mg compresse a rilascio prolungato
Latvia	Klatex 500 mg ilgstošās darbības tabletes
The Netherlands	Clarithromycine retard 500 mg Teva, tabletten met gereguleerde afgifte
Portugal	Claritromicina Teva, 500 mg comprimido de libertação prolongada
Spain	Claritromicina Unidia Teva 500 mg comprimidos de liberación prolongada EFG
United Kingdom	Zachte XL 500 mg Prolonged Release Tablets

This leaflet was last revised in April 2018.