

Package leaflet: Information for the user

Clarie XL 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

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2. What you need to know before you take Clarie XL
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1. What Clarie XL is and what it is used for

Clarie XL contains the active ingredient clarithromycin. Clarithromycin is an antibiotic, which can be used to treat the following bacterial infections:

- Community-acquired pneumonia (infection of the lungs, developed outside of hospitals or extended-care facilities)
- Short-term worsening of chronic bronchitis caused by bacterial infection
- Bacterial sinusitis (infection of the sinuses)
- Bacterial pharyngitis and tonsillitis (infection of the throat or tonsils)
- Skin and soft tissue infections (mild to moderate severity)

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

Do not take Clarie XL

- if you are allergic to clarithromycin, other macrolides (similar antibiotics), or any of the other ingredients of this medicine (listed in Section 6). An allergic reaction may include rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.
- 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
- 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 cholesterol-lowering drugs (lovastatin or simvastatin)
- if you have abnormally low levels of potassium in your blood (hypokalaemia)
- if you have severe liver problems in combination with kidney problems
- if you are taking colchicine (used to treat gout)

Warnings and precautions

Talk to your doctor or pharmacist before taking Clarie XL if you:

- suffer from problems with your kidneys
- suffer from problems with your liver
- suffer from problems with your heart
- are pregnant or breast-feeding
- are taking drugs called triazolam or midazolam (usually taken for sedation or sleeping)
- are taking aminoglycosides (antibiotic drugs)
- are taking cholesterol-lowering drugs (statins)
- are taking drugs that lower your blood sugar (oral hypoglycaemic agents) or insulin
- are taking blood thinners (oral anticoagulants like warfarin)
- have muscle problems known as myasthenia gravis
- have abnormally low levels of magnesium in your blood (hypomagnesaemia)
- 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 Clarie XL').

Other medicines and Clarie XL

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

You should not be given Clarie XL if you are taking any one of the following medicines (see section “**Do not take Clarie XL**”)

- terfenadine or astemizole (for hay fever or allergy),
- cisapride (for stomach disorders),
- pimozide (for mental illness),

as these medicines may cause you to experience a life-threatening irregular heartbeat.

- ergotamine type drugs (usually used for migraine, eg ergotamine or dihydroergotamine),
as these medicines may cause narrowing of the blood vessels leading to a restriction of blood supply to body tissues.

- lovastatin or simvastatin (cholesterol-lowering drugs),
as these medicines may lead to pain or weakness in muscles, or abnormal muscle breakdown which can lead to kidney problems.

- colchicine (a treatment for gout),
as clarithromycin may lead to increased concentrations of this drug in your body, increasing the risks of side effects and leading to potential toxicity.

- ticagrelor (a blood-thinning drug)
- ranolazine (used to treat angina).

Your doctor may need to control blood levels or effects, to adjust the dosage, or to interrupt (for some time) the treatment if clarithromycin is used at the same time with medicines containing one of the substances listed below:

- digoxin (for heart failure) as it may cause an irregular heart beat. Clarithromycin may also lead to increased concentrations of this drug in your body, increasing the risk of side effects
- quinidine or disopyramide (for heartbeat disorders) as these medicines may cause you to experience a life-threatening irregular heart beat
- midazolam (sedatives/sleeping pills), triazolam (sleeping pills) or alprazolam (for anxiety) as these medicines may cause sleepiness or confusion
- ritonavir, atazanavir, saquinavir (HIV treatments) as this may lead to increased concentrations of either these medicines or clarithromycin in your body, increasing the risks of side effects
- efavirenz, nevirapine, etravirine (HIV treatments) as these medicines may lead to decreased concentrations of clarithromycin in your body, altering the effectiveness of your drug

- zidovudine (HIV treatment) as clarithromycin may lead to decreased absorption of this drug in your body, altering the effectiveness of the drug
- rifabutin, rifampicin, rifapentine (antibiotics) as these medicines may lead to decreased concentrations of clarithromycin in your body, altering the effectiveness of your drug
- warfarin or acenocoumarol (blood thinners) as these medicines may alter the rate at which your blood clots which might result in toxic effects
- cholesterol-lowering drugs (atorvastatin, rosuvastatin) as these medicines may lead to pain or weakness in muscles, or abnormal muscle breakdown which can lead to kidney problems. Clarithromycin may also lead to increased concentrations of these drugs in your body, increasing the risks of side effects
- itraconazole or fluconazole (used in fungal infections) as this may lead to increased concentrations of either these medicines or clarithromycin in your body, increasing the risks of side effects

The following medicines, for which clarithromycin may lead to increased concentrations of these drugs in your body, increasing the risks of side effects:

- valproate, phenytoin or carbamazepine (for epilepsy)
- cilostazol (a treatment for leg cramps)
- methylprednisolone (used to treat inflammation)
- sildenafil, tadalafil, vardenafil (treatment for erection problems)
- vinblastine (a cancer treatment)
- tolterodine (used for urinary frequency)
- eletriptan (used for migraine)
- aprepitant (used to prevent nausea and vomiting after chemotherapy)
- halofantrine (used to treat malaria)
- omeprazole (for indigestion)
- ziprasidone (for schizophrenia)
- ciclosporin, tacrolimus, sirolimus (to help prevent rejection after a transplant)
- theophylline (for asthma)

Other interactions include:

- St John's Wort (herbal product to treat depression).
- Drugs that lower your blood sugar, e.g. insulin, nateglinide, repaglinide.
- Aminoglycosides (antibiotics) e.g. gentamicin
- Calcium channel blockers e.g. verapamil, amlodipine, diltiazem (used to treat high blood pressure or heartbeat disorders)

It may still be all right for you to take the tablets and your doctor will be able to decide what is suitable for you.

Clarie XL 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.

Small amounts of clarithromycin can pass into breast milk.

Clarie XL should not be given to pregnant or breast-feeding mothers unless the benefits to the mother outweigh the risks to the baby.

Driving and using machines

Clarie XL may cause dizziness. If affected you should not drive or use machines.

Clarie XL 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 Clarie XL

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

Your tablets must be swallowed whole and not chewed. Clarie XL should be taken with food.

Adults and children over 12 years

The recommended dose is one tablet (500 mg) once daily.

Your doctor may increase the dose to two tablets daily (1000 mg) in more severe infections.

Your dose must be taken at the same time every day.

The usual duration of treatment is 6 to 14 days.

Children under 12 years

Clarie XL is not suitable for children under 12 years of age. Your doctor can advise you of other clarithromycin medicines which may be more suitable for children in this age group, such as clarithromycin suspension.

If you take more Clarie XL than you should

If you take more tablets than you should contact your doctor or hospital immediately. If you take too many tablets it may cause gastrointestinal symptoms such as vomiting and stomach pain.

If you forget to take Clarie XL

If you forget to take your 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 Clarie XL

You should take the tablets for as long as your doctor has told you to even if the symptoms disappear, otherwise your infection 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 this medicine and contact your doctor immediately if any of the following side effects occur:

- Swelling of the face, lips, tongue or throat leading to severe difficulty in swallowing or breathing, skin flushing and/or dizziness or fainting (severe allergic reaction)
- Severe or prolonged diarrhoea which may contain blood or mucous, fever or painful abdominal cramps (pseudomembranous colitis)
- Severe skin reactions such as blistering of the skin, mouth, eyes or genitals (Stevens-Johnson syndrome, toxic epidermal necrolysis)
- A red, scaly rash with bumps under the skin and blisters (exanthematous pustulosis)
- Drug rash with eosinophilia (type of white blood cells increase) and systemic symptoms (DRESS)
- Loss of appetite, yellowing of the skin and whites of the eyes, dark urine, itching or tender tummy (severe liver failure)

The following side effects have been reported:

Common: may affect up to 1 in 10 people

- **Psychiatric disorders:** difficulty in sleeping
- **Nervous system disorders:** headache, taste disturbance, taste perversion
- **Digestive system disorders:** abdominal (tummy) pain, diarrhea, indigestion, feeling sick, vomiting
- **Liver, gall bladder and bile duct disorders:** altered liver function tests
- **Skin disorders:** rash, increased sweating
- **Kidney disorders:** increased levels of urea (a measure of nitrogen) in the blood
- **Vascular disorders:** widening of blood vessels

Uncommon: may affect up to 1 in 100 people

- **Infections:** gastroenteritis (inflammation of stomach and intestines), fungal infection, vaginal bacterial or fungal infection, skin inflammation
- **Blood disorders:** leucopenia and neutropenia (reduction in the number of white blood cells, which makes infections more likely), eosinophilia (blood disorder), thrombocythaemia (increase in blood platelets, which increases risk of bleeding or blood clots)
- **Immune system disorders:** allergic reactions ranging from urticaria (nettle rash), mild skin eruptions and angioedema (swelling of the hands and face) to anaphylaxis (severe allergic reaction), hypersensitivity
- **Metabolism and nutrition disorders:** anorexia (loss of appetite), decreased appetite
- **Psychiatric disorders:** nervousness, anxiety
- **Nervous system disorders:** dizziness, tremor (shaking), sleepiness, loss of consciousness, movement disorder
- **Ear and labyrinth disorders:** tinnitus (ringing in the ears), vertigo (spinning sensation), hearing impaired
- **Heart disorders:** heart rhythm disturbances, palpitations (sensations of irregular and/or forceful beating of the heart), ECG abnormalities
- **Respiratory disorders:** shortness of breath or other problems with breathing including asthma, nose bleed
- **Digestive system disorders:** constipation, dry mouth, belching, flatulence (wind), gastroesophageal reflux disease, inflammation or ulceration of the mouth e.g. mouth ulcers and cold sores, inflammation of the tongue, inflammation of the oesophagus and stomach lining, rectal pain, bloating
- **Liver, gall bladder and bile duct disorders:** hepatitis (inflammation of the liver), cholestasis (obstruction of bile) with or without jaundice (yellowing of the skin and whites of the eyes), increased liver enzymes in blood.
- **Skin disorders:** redness of skin, scaling, itching, rash with raised bumps, rash with pus, dry skin or eczema, nettle rash
- **Musculoskeletal disorders:** joint or muscle pain, muscle stiffness
- **Kidney disorder:** altered kidney function or blood tests
- **General disorders:** feeling of weakness or discomfort, lethargy, general feeling of being unwell, chest pain or any other pain, chills, tiredness, fever
- **Abnormal laboratory test results:** altered liver function tests or blood tests,

Very rare: may affect up to 1 in 10,000 people

- **Nervous system disorders:** paraesthesia (tingling or numbness of limbs)

Not known: frequency cannot be estimated from the available data

- **Infections:** erysipelas or erythrasma (infections of the skin)
- **Blood disorder:** agranulocytosis (severe reduction in white blood cells with an increased risk of infection), thrombocytopenia (reduction in blood platelets, which increases risk of bleeding or bruising)

- **Immune system disorders:** Anaphylactic reaction (severe allergic reaction), angioedema (swelling of the face, lips and tongue)
- **Metabolism and nutrition disorder:** hypoglycaemia (low blood sugar)
- **Psychiatric disorder:** mania, abnormal dreams, confusional state, , depersonalization (out of body feeling), disorientation (not knowing where you are), hallucination, depression
- **Nervous system disorders:** fits, loss of taste, smell alteration, loss of ability to smell
- **Ear and labyrinth disorders:** irreversible hearing loss
- **Heart disorders:** heart rhythm disturbances, life-threatening irregular heart beat
- **Vascular disorders:** Bleeding
- **Digestive system disorders:** pancreatitis (inflammation of the pancreas), discolouration of tongue and teeth
- **Skin disorders:** acne
- **Musculoskeletal disorders:** Rhabdomyolysis (pain or weakness in muscles, or abnormal muscle breakdown which can lead to kidney problems), myopathy (muscular weakness)
- **Kidney disorders:** kidney failure, interstitial nephritis (inflammation of the kidneys)
- **Abnormal laboratory test results:** International normalised ratio increased and prothrombin time prolongation (increased blood clotting time), urine colour abnormal

You may get side effects which you are not aware of, such as changes in the number of certain blood cells, other blood components or liver enzymes. Your doctor may choose to do blood tests to check this.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard, or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. How to store Clarie XL

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

Do not store above 30°C.

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

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 protect the environment.

6. Content of the pack and other information

What Clarie XL contains:

- The active substance is: Clarithromycin citrate equivalent to clarithromycin 500 mg.
- The other ingredients are: lactose monohydrate, hypromellose, hypromellose phthalate, talc, magnesium stearate, macrogol, quinoline yellow aluminium lake (E104), titanium dioxide (E171).

What Clarie XL looks like and contents of the pack

Clarie XL tablets are yellow, oblong prolonged-release tablets.

Your tablets come in blister packs in pack sizes of 7 or 14 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder is:

TEVA UK Limited, Brampton Road, Hampden Park, Eastbourne, East Sussex BN22 9AG, UNITED KINGDOM

Manufacturer is:

TEVA UK Limited, Eastbourne, BN22 9AG

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