

PACKAGE LEAFLET: INFORMATION FOR THE USER

Clorom 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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1. What Clorom XL Tablets are and what they are used for

Clorom XL 500 mg Prolonged Release Tablets (Called Clorom XL Tablets in this leaflet) contain the active ingredient clarithromycin citrate. Clarithromycin belongs to a group of medicines called macrolide antibiotics. Antibiotics stop the growth of bacteria (bugs) which cause infections. Clorom XL Tablets are used to treat infections such as:

1. Chest infections such as bronchitis and pneumonia
2. Throat and sinus infection
3. Mild to moderate skin and tissue infections, e.g. cellulitis, folliculitis or erysipelas.

Clorom XL Tablets are used in adults and children 12 years and older.

2. What you need to know before you take Clorom XL Tablets

Do not take Clorom XL Tablets

- If you know that you are allergic to clarithromycin or other antibiotics from the same drug class (macrolide antibiotics) such as erythromycin or azithromycin, or if you are allergic to any of the other ingredients of this medicine (listed in section 6).
- If you are taking ergot alkaloids (e.g. ergotamine or dihydroergotamine tablets) or use ergotamine inhalers for migraine, or oral midazolam (for anxiety or to help sleep).
- If you are taking other medicines which are known to cause serious disturbances in heart rhythm.
- If you are taking medicines called astemizole or terfenadine (medicine taken for hay fever or allergies), cisapride or domperidone (used for stomach disorders) or pimozone (medicine used to treat certain psychiatric diseases), as taking these medicines with Klacid can cause serious disturbances in heart rhythm.

- If you are taking ticagrelor, ivabradine or ranolazine (medicine taken for angina or to reduce the chance of heart attack or stroke).
- If you have abnormally low levels of potassium or magnesium in your blood (hypokalaemia or hypomagnesaemia).
- If you are taking drugs for high cholesterol (such as lovastatin or simvastatin).
- If you are taking a medicine containing lomitapide.
- If you have severe liver and/or severe kidney problems.
- If you had or currently have heart rhythm disorders (ventricular cardiac arrhythmia, including torsades de points) or abnormality of electrocardiogram (ECG, electrical recording of the heart) called “long QT syndrome”.
- If you are taking colchicine (for gout).

Warning and precautions

Talk to your doctor or pharmacist before taking Clorom XL Tablets:

- If you are pregnant or breast feeding (see Pregnancy and breast-feeding).
- If you develop severe or prolonged diarrhoea during or after taking Clorom XL Tablets, consult your doctor immediately.
- If you have certain heart problems (coronary artery disease, severe cardiac insufficiency, abnormal heart rhythms or clinically relevant slow heart rate).
- If you have impaired kidney function or impaired hepatic function as a dose reduction may be necessary.

Children under 12 years

Clorom XL Tablets are not suitable for use in children under 12 years of age.

Other medicines and Clorom XL Tablets

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

Do not take Clorom XL Tablets if you are taking any of the medicines listed in the section “Do not take Clorom XL Tablets” above.

Tell your doctor if you are taking any of the following medicines as the dose may need to be changed or you may need to have regular tests performed:

- digoxin, quinidine or disopyramide (heart drugs)
- warfarin, or any other anticoagulant e.g. dabigatran, rivaroxaban, apixaban, edoxaban (blood thinner)
- eletriptan (for migraine)
- carbamazepine, valproate, phenobarbital or phenytoin (for epilepsy or bipolar disorder (manic-depression))
- St. John’s Wort (a herbal product used to treat depression)
- theophylline (for asthma or emphysema)
- triazolam, alprazolam or intravenous or buccal (oromucosal) midazolam (for anxiety or to help sleep)
- omeprazole (for stomach disorders)
- quetiapine or ziprasidone (for schizophrenia or other psychiatric conditions)
- zidovudine, ritonavir, atazanavir, saquinavir, nevirapine, efavirenz or etravirine (for HIV)
- rifabutin, rifapentine or rifampicine (antibiotics effective against some infections such as tuberculosis)

- itraconazole or fluconazole (for fungal infections)
- sildenafil, tadalafil or vardenafil (for erectile dysfunction)
- tolterodine (for bladder problems)
- methylprednisolone (a steroid to treat inflammation)
- ibrutinib or vinblastine (for cancer treatment)
- aprepitant (for preventing vomiting during chemotherapy)
- cilostazol (to improve circulation in the legs)
- any betalactam antibiotics (certain penicillins and cephalosporin antibiotics)
- tacrolimus, sirolimus or cyclosporin (to help organ transplants)
- nateglinide, repaglinide, sulphonylureas or insulin (medicines used to treat diabetes)
- aminoglycosides (medicines used as antibiotics to treat infections)
- calcium channel blockers (medicines to treat high blood pressure).
- 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)

Clorom XL Tablets with food and drink

The tablets 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 before taking this medicine as the safety of Clorom XL Tablets in pregnancy and breast-feeding is not known.

Driving and using machines

Clorom XL Tablets may make you feel dizzy or drowsy. If they affect you in this way do not drive, operate machinery or do anything that requires you to be alert.

Clorom XL Tablets contain lactose

Clorom XL Tablets contain 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 Clorom XL Tablets

Do not give Clorom XL Tablets to children under 12 year. 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.

The usual dose of Clorom XL Tablets for adults and children over 12 years 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. Clorom XL Tablets should be taken with food and must be swallowed whole and not chewed.

If you take more Clorom XL Tablets than you should

If you accidentally take more Clorom XL Tablets in one day than your doctor has told you to, or if a child accidentally swallow some tablets, contact your doctor or nearest hospital emergency department immediately. An overdose of Clorom XL Tablets is likely to cause vomiting and stomach pains and there is a possibility of allergic reactions.

If you forget to take Clorom XL Tablets

If you forget to take a dose of Clorom XL Tablets, take it as soon as you remember. Do not take more tablets in one day unless your doctor has told you to.

If you stop taking Clorom XL Tablets

Do not stop taking Clorom XL Tablets, even if you feel better. It is Important to take the tablet 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 any of the following happen, stop taking Clorom XL Tablets and tell your doctor immediately or go to your nearest hospital emergency department:

- Severe or prolonged diarrhoea, which may have blood or mucus in it, stomach pain and fever. Diarrhoea may occur over two months after treatment with clarithromycin.
- 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 and may need emergency treatment.
- Loss of appetite, yellowing of the skin (jaundice), dark urine, light-coloured stools, itching or tenderness in the abdomen. Contact your doctor immediately as these may be signs of liver failure.
- Severe skin reactions, potentially life-threatening, such as blistering of the skin, mouth, lips, eyes and genitals (symptoms of a rare allergic reaction called Stevens-Johnson syndrome/toxic epidermal necrolysis) or a red, scaly rash with bumps under the skin and blisters (symptoms of exanthematous pustulosis). The frequency of this side effect is not known (cannot be estimated from the available data).
- Muscle pain or weakness known as rhabdomyolysis (a condition which causes the breakdown of muscle tissue which can result in kidney damage).

OTHER SIDE EFFECTS:**Common (may affect up to 1 in 10 people):**

- Insomnia
- Headache
- Changes in the sense of taste (dysgeusia)
- Diarrhoea
- Vomiting
- Nausea
- Feeling or being sick
- Indigestion, abdominal pain
- Abnormal blood test (raised liver enzymes)

- Rash
- Increased sweating.

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

- Infections such as infections of the stomach and intestine, inflammation of the skin caused by infections, oral or vaginal thrush and vaginal infections
- Low levels of white blood cells, and other white blood cell disorders
- Allergic reactions such as rashes, swelling, itching, hives
- Decreased appetite, loss of appetite
- Anxiety
- Nervousness
- Fainting, dizziness, tremors, drowsiness
- Ringing in the ears, vertigo (sensation of spinning) and ear disorders
- Lack of energy, chest pain, swelling of the face, a feeling of general discomfort, pain and thirst
- Changes in heart rhythm, electrocardiogram QT prolonged (abnormal findings in the electrocardiogram)
- Asthma and shortness of breath
- Nosebleed
- Constipation, rectal pain, dry mouth, excess gas in the stomach, burping, and flatulence (wind)
- Heartburn, gastritis (inflammation of gastric mucosa), stomatitis (inflammation of the mouth), glossitis (inflammation of the tongue)
- Muscle pain, muscle cramps
- Chills, tiredness, pyrexia.

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

- Bacterial infection of the outer layers of the skin
- Psychiatric disorders such as abnormal dreams, being in a state of confusion, depersonalisation, disorientation, hallucination (seeing things), psychotic disorder, depression, mania
- Convulsions or fits, loss of taste, abnormal smell or loss of smell, pins and needles
- Deafness
- Ventricular fibrillation (uncoordinated contraction of the heart muscle)
- Bleeding
- Kidney disorders including inflammation of the kidney, and the presence of blood in the urine
- Acute pancreatitis (upper abdominal pain, going through to the back, which may be associated with loss of appetite, feeling or being sick)
- Tongue discolouration, tooth discolouration
- Acne
- Low blood counts (signs may include pale skin and tiredness) and low counts of certain blood elements that help fight infection (signs may include sore throat, fever, feeling very sick, easy bruising, bleeding)
- Muscle weakness.

If you have a blood test while taking Clorom XL Tablets, it may show a decrease in clotting factor and an increase in other enzymes. Protein in the urine may also be detected.

If you develop diarrhoea during or after taking Clorom XL Tablets, consult your doctor immediately. While diarrhoea can occur as a reaction to the medicine, it can also be a sign of a more serious condition. Your doctor will know how to distinguish between the two conditions.

In the unlikely event that your infection has been caused by a germ that Clorom XL Tablets cannot treat, your symptoms may get worse. If this happens, be sure to consult your doctor.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 at:

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 Clorom XL Tablets

Keep out of the sight and reach of children.

This medicinal product does not require any special storage conditions.

Do not use Clorom XL Tablets after the expiry date which is stated on the carton. 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 Clorom XL Tablets contain

The active substance is clarithromycin citrate. Each prolonged-release tablet contains clarithromycin citrate equivalent to clarithromycin 500mg.

The other ingredients in the tablet core are lactose monohydrate, hypromellose, hypromellose phthalate, talc, magnesium stearate. The tablet coating contains hypromellose, macrogol, quinoline yellow aluminium lake (E104), talc and titanium dioxide (E171).

What Clorom XL Tablets looks like and contents of the pack

Clorom XL Tablets are yellow coloured, film coated, oblong shaped, biconvex tablets, with both sides plain.

They are available in blister packs of 7, 10, 14, 20, 28, 30, 56, 60, 84, 90, 100 and 112 film coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Morningside Healthcare (Malta) Ltd.
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Manufacturer

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