

PACKAGE LEAFLET: INFORMATION FOR THE USER
Clorom XL 500mg Prolonged Release Tablets

Clarithromycin



Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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.

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1. What Clorom XL Tablets are and what they are used for
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1. WHAT CLOROM XL TABLETS ARE AND WHAT THEY ARE USED FOR

Clorom XL 500mg Prolonged Release Tablets (Called Clorom XL Tablets in this leaflet) contain the active ingredient clarithromycin citrate. Clarithromycin belongs to a group of drugs called macrolide antibiotics which are used in the treatment of:

1. chest infections such as bronchitis and pneumonia
2. sinus infection
3. skin and soft tissue infections (mild to moderate severity)

2. BEFORE YOU TAKE CLOROM XL TABLETS

Do not take Clorom XL Tablets if you

- are allergic to clarithromycin or other macrolide antibiotics such as erythromycin or azithromycin.
- are taking the following, you should consult your doctor for advice on alternative medicines:
 - colchicine (for gout)
 - ergotamine or dihydroergotamine tablets or use ergotamine inhalers for migraine
 - cisapride (for stomach disorders), pimozone (for some mental illnesses), terfenadine and astemizole (for hay fever or allergy) or other macrolide antibiotics, as combining these drugs with clarithromycin can sometimes cause serious disturbances in heart rhythm. Consult your doctor for advice on alternative medicines.
- have serious kidney or liver problems, consult your doctor immediately.
- have or someone in your family is known to have an abnormality of electrocardiogram (ECG) called 'long QT syndrome'.

Take special care with CLOROM XL Tablets

- if you have liver problems
- if you have kidney problems
- If you develop severe or prolonged diarrhoea during or after taking Clorom XL Tablets
- If your potassium levels are low (hypokalaemia).

If any of the above apply to you, please tell your doctor immediately.

Taking other medicines

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

- Digoxin, quinidine or disopyramide (heart drugs)
- Warfarin or other drugs to thin the blood
- Ergotamine, dihydroergotamine or eletriptan (for migraine)
- Carbamazepine, valproate or phenytoin (drugs for epilepsy)
- Colchicine (for gout)
- Theophylline (helps breathing)
- Terfenadine or astemizole (for hay fever or allergy)
- Triazolam, alprazolam or midazolam (sedatives)
- Cilostazol (for poor circulation)
- Simvastatin or lovastatin (for high cholesterol)

- Cisapride or omeprazole (for stomach disorders)
- Itraconazole or fluconazole (for fungal infections)
- Tolterodine (for overactive bladder)
- Aprepitant (for preventing vomiting during chemotherapy)
- Methylprednisolone (a corticosteroid)
- Vinblastine (for treatment of cancer)
- Sildenafil, tadalafil or vardenafil (for impotence)
- Cyclosporin (immune suppressant)
- Pimozide or ziprasidone (for psychiatric conditions)
- Zidovudine, ritonavir, atazanavir, saquinavir, nevirapine or efavirenz (anti-viral [anti-HIV] drugs)
- Rifabutin or rifampicin (for treatment of some infections such as tuberculosis)
- Tacrolimus (for organ transplants).

Clorom XL Tablets do not interact with oral contraceptives.

Taking 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

Do not take Clorom XL Tablets if you are pregnant or breast feeding without consulting your doctor or pharmacist.

Driving and using machines

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

Important information about some of the ingredients of Clorom XL Tablets

Clorom XL Tablets contain lactose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE CLOROM XL TABLETS

Always take Clorom XL Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The usual dose is:

Adults and children over 12 years: One (1) 500mg tablet daily for seven (7) to fourteen (14) days. Your doctor may increase the dose to two (2) 500mg tablets daily in severe infections.

Children under 12 years: Not recommended.

If you take more Clorom XL Tablets than you should

If you (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any contact your nearest hospital casualty department or tell your doctor immediately.

If you forget to take Clorom XL Tablets

Take the missed dose as soon as you remember, unless it's nearly time for the next dose. Do not take two doses at the same time to make up for forgotten individual doses.

If you stop taking Clorom XL Tablets

Do not stop taking Clorom XL Tablets 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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, clarithromycin can cause side effects, although not everybody gets them.

Very common: Affects more than 1 person in 10.

Common: Affects 1 to 10 people in 100.

Uncommon: Affects 1 to 10 people in 1,000.

Rare: Affects 1 to 10 people in 10,000.

Very rare: Affects less than 1 person in 10,000.

Not known: Frequency cannot be estimated from the available data.



If any of the following happen, stop taking Clorom XL and tell your doctor immediately or go to your nearest hospital emergency department:

- Severe pain in the abdomen and back caused by inflammation of the pancreas.
- Severe diarrhoea with blood in the stools during or after taking Clorom XL Tablets. Diarrhoea may occur over two months after treatment with Clorom XL Tablets.
- Dark urine, pale stools, jaundice (yellowing of the skin and/or eyes), nausea, fever.
- Allergic reactions including rashes have been reported with Clorom XL Tablets. 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).
- In the unlikely event that your infection has been caused by a bug which Clorom XL Tablets cannot treat, your symptoms may get worse. If this happens, you should consult your doctor.

Common side effects (Affects more than 1 person in 10) include;

- feeling sick
 - vomiting
 - stomach pain
 - indigestion
 - diarrhoea
- headache
- changes in sense of taste or smell

Uncommon side effects (Affects 1 to 10 people in 1000) include;

- 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, increased appetite and other nutrition disorders
- Psychiatric disorders such as depression, difficulty sleeping (insomnia), nervousness and feeling sleepy.
- Dizziness, headache and tremor.
- Conjunctivitis (inflammation of the eyes) and visual disturbances.
- Ringing in the ears, vertigo and ear disorders.
- Vasodilation (flushing).
- Asthma, 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 discoloration, 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, joint or muscle pain.
- Kidney disorders including the presence of protein and blood in urine, passing urine with pus (if you have a urine test).
- Genital discharge.
- Lack of energy, chest pain, swelling of face, a feeling of general discomfort, pain and thirst.
- If you have a blood test while taking Clorom XL, 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, prothrombin time prolongation (increased blood clotting time) and an increase in other enzymes may also be detected. Changes in laboratory test values such as chloride, uric acid and calcium.

Very rare side effects: (Affects less than 1 person in 10,000) include;

- Tingling or numbness of limbs

Not known frequency of occurrence (frequency cannot be estimated from the available data) include;

- Decrease in platelets (blood cells that help you stop bleeding)
- Low blood sugar levels

- 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
- Abnormal electric activity tracing of the heart (ECG), changes in heart rhythm
- Inflammation of the tongue and tooth discoloration
- Liver failure, abnormal liver function or hepatitis
- Inflammation of the kidneys and
- Liver enzymes increased.

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.

Clarithromycin may worsen the symptoms of myasthenia gravis (a condition in which the muscles become weak and tire easily) in patients who already suffer from this condition.

5. HOW TO STORE CLOROM XL TABLETS

This medicinal product does not require any special storage conditions.

Keep out of the reach and sight of children.

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.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER 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, Quinaline 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 and Manufacturer

Marketing Authorisation Holder

Morningside Healthcare Ltd
 115 Narborough Road
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Manufacturer

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

UK: Xetinin XL
 IE: Clorom XL

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