

Package leaflet: Information for the patient

Clorom 250 mg Film-coated tablets

Clorom 500 mg Film-coated 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 Clorom is and what it is used for
2. What you need to know before you take Clorom
3. How to take Clorom
4. Possible side effects
5. How to store Clorom
6. Contents of the pack and other information

1 What Clorom is and what it is used for

Clorom is an antibiotic which belongs to the group of macrolide antibiotics. It stops the growth of certain bacteria.

Clorom is used in adults and adolescents (12 years and older) to treat infections caused by bacteria which are sensitive to clarithromycin, for example:

- in the **bronchi** and **lungs**
- in the **sinuses** and **throat**
- on the **skin** and in the **muscles**
- for **gastric ulcers** caused by the bacterium *Helicobacter pylori*.

2 What you need to know before you take Clorom

Do not take Clorom

- if you are **allergic** to clarithromycin, other macrolide antibiotics or any of the other ingredients of this medicine (listed in section 6)
- if you or someone in your family has a history of **heart rhythm disorders** (ventricular arrhythmia, including torsade de pointes) or abnormality of electro-cardiogram (ECG, electrical recording of the heart) called “long QT syndrome”
- if you suffer from severe **liver** failure and **kidney** problems **at the same time**
- if you have abnormally low levels of potassium or magnesium in your blood (hypokalaemia or hypomagnesaemia)
- if you are taking
 - **ticagrelor, ivabradine** or **ranolazine** (for angina or to reduce the chance of heart attack or stroke)
 - **ergotamine, dihydroergotamine** (medicines to treat migraine)
 - **oral midazolam** (for anxiety or to help sleep)
 - **cisapride** and **domperidone** (gastric medicine)
 - **pimozide** (antipsychotic)
 - **terfenadine, astemizole** (hay fever, antiallergics)
 - **lovastatin, simvastatin** (medicines to lower cholesterol)
 - a medicine containing **lomitapide**
 - **colchicine** (to treat gout)

- other medicines which are known to cause serious disturbances in heart rhythm.

Warnings and precautions

Talk to your doctor or pharmacist before taking Clorom

- if you have reduced **liver** or **kidney function**
- if you develop **severe or prolonged diarrhoea** (pseudomembranous colitis) during or after taking Clorom, consult your doctor immediately. Inflammation of the colon (Pseudomembranous colitis) has been reported with nearly all antibacterial medicines including clarithromycin.
- if you have **heart problems**.

Other medicines and Clorom

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

Clorom must not be taken with ergot alkaloids, astemizole, terfenadine, cisapride, domperidone, pimozone, ticagrelor, ranolazine, colchicine, some medicines for treating high cholesterol and medicines that are known to cause serious disturbances in heart rhythm (see under **Do not take Clorom**).

Certain other medicines may affect the effectiveness of Clorom or vice-versa. Such medicines include:

Clorom may increase the effect of the following medicines:

- Ibrutinib (chronic lymphocytic leukaemia)
- Alprazolam, triazolam, intravenous or buccal (oromucosal) midazolam (for anxiety or to help sleep)
- Digoxin, verapamil, amlodipine, diltiazem (heart medicines)
- Theophylline (antiasthmatic)
- Warfarin or any other anticoagulant e.g. dabigatran, rivaroxaban, apixaban, edoxaban (used to thin your blood)
- Atorvastatin, rosuvastatin (cholesterol lowering agents)
- Cyclosporine, sirolimus, tacrolimus (immunosuppressants)
- Carbamazepin, phenytoin, valproate (medicines to treat epilepsy)
- Cilostazol (used to improve circulation in the legs)
- Insulin and other medicines for the treatment of diabetes (such as nateglinide or repaglinide)
- Methylprednisolone (a cortisone to treat inflammation)
- Omeprazole (gastric medicine)
- Sildenafil, tadalafil, vardenafil (medicines to treat erectile dysfunction)
- Tolterodine (to treat overactive bladder syndrome)
- Vinblastine (medicine for cancer therapy)
- Medicines with the risk to affect hearing, especially aminoglycosides, such as gentamicin or neomycin (group of antibiotics).

Both, the effect of Clorom and the effect of the following medicines may be increased when taken together:

- Atazanavir, saquinavir (medicines to treat HIV)
- Itraconazole (a medicine to treat fungal infections).

If your doctor has specifically recommended to take Clorom and any of the above mentioned medicines at the same time, your doctor may need to monitor you more closely.

The following medicines may weaken the effect of Clorom:

- Rifampicin, rifabutin, rifapentine (antibiotics)
- Efavirenz, etravirine, nevirapine (medicines to treat HIV)
- Phenytoin, carbamazepine, phenobarbital (antiepileptic)
- St John's Wort (herbal product to treat depression).

This is also important if you are taking medicines called:

- **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).

Please note:

- **Ritonavir** (antivirals) and **fluconazole** (a medicine to treat fungal infections) may increase the effect of Clorom.
- Clorom may weaken the effect of **zidovudine** (medicines to treat HIV). In order to avoid this you should leave a 4 hour interval between taking these medicines.
- The use of Clorom at the same time as **digoxin, quinidine, disopyramide** or **verapamil** (heart medicines), or **other macrolide antibiotics** may cause cardiac arrhythmia.
- The use of Clorom at the same time as **disopyramide** may cause low blood sugar levels (*hypoglycaemia*).

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.

Driving and using machines

Clorom has generally no effect on the ability to drive or use machines but may cause side effects, such as dizziness, confusion and disorientation. If you feel affected you should not drive, operate machinery or take part in activities where you may put yourself or others at risk.

Visual impairment and blurred vision may have an effect on a patient's ability to drive or operate machinery.

Clorom contains lactose and sodium

This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium-free'.

3 How to take Clorom

The doctor will prescribe the individual dosage which is appropriate for you. Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Dosage

The usual dose is:

Adults and adolescents (12 years and older)

Clorom 250 mg film-coated tablets:

1 Clorom 250 mg film-coated tablet twice daily.

The dosage may be increased to 2 Clorom 250 mg film-coated tablets twice daily.

Clorom 500 mg film-coated tablets:

½ Clorom 500 mg film-coated tablet twice daily.

The dosage may be increased to 1 Clorom 500 mg film-coated tablet twice daily.

Gastric ulcer caused by the bacterium *Helicobacter pylori*

2 Clorom 250 mg film-coated tablets twice daily or 1 Clorom 500 mg film-coated tablet twice daily in combination with suitable antibiotics and medicines which are used for the treatment of excess gastric acid production.

Children (younger than 12 years):

Use for children under the age of 12 years is not recommended.
For these patients other pharmaceutical forms e.g. suspensions are available.

Severe kidney failure:

Your doctor will lower the dose.

Method of use

For oral use.

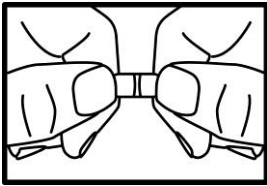
Take a glass of water with the medicine.

The medicine may be taken with or without food.

Clorom 500 mg film-coated tablets:

Tablet dividing instructions

Divide the film-coated tablets as illustrated in this figure:



Duration of treatment

- The duration of treatment is generally 6–14 days. Treatment should continue for at least 2 days after the symptoms have disappeared.
- In the case of streptococcal infections the minimum duration of therapy should be 10 days.
- Treatment of gastric ulcer due to *Helicobacter pylori* should be continued for 7 days.

If you take more Clorom than you should

If you have taken too much Clorom, contact your doctor or hospital as soon as possible.

Symptoms of overdosage may be gastrointestinal symptoms.

If you forget to take Clorom

If you forget to take Clorom, continue treatment following the normal dosage, recommended by your doctor.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Clorom

It is important that you take your medicine in accordance with the doctor's instructions. Do not suddenly stop using Clorom without discussing it first with your doctor. Otherwise symptoms may return.

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.

Serious side effects:

Contact your doctor or the **casualty department** at your nearest hospital **immediately** if you have any of the following symptoms of a **severe allergic reaction**:

- sudden difficulty in breathing, speaking and swallowing
- extreme dizziness or collapse
- severe or itchy skin rash, especially if this shows blistering and there is soreness of the eyes, mouth or genital organs.

Contact your doctor as soon as possible if you develop:

- **severe** and persistent **diarrhoea** during or after treatment, sometimes bloody-slimy and/or with cramp-like abdominal pain. This can be a sign of a serious bowel inflammation. Your doctor may discontinue treatment. Do not take medicines that reduce bowel movements.
- **liver problems** with possible signs such as
 - loss of appetite
 - yellowing of your skin or whites of your eyes (jaundice)
 - unusually dark urine, pale stools
 - itching of the skin
 - abdominal pain.
- feeling your **heartbeat** or irregular heartbeat
- inflammation of the pancreas, which causes **severe pain in the abdomen and back**
- a red, scaly rash with bumps under the skin and blisters (exanthematous pustulosis).

Other side effects:

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

- sleeplessness
- headache
- changes in the senses of taste
- stomach-ache, feeling sick, vomiting, diarrhea, digestive disorders
- abnormal liver function tests
- rash
- sweating
- widening of blood vessels.

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

- yeast infections (candidiasis) for example in the mouth
- infections of the vagina
- reduced number of white blood cells (leucopenia, neutropenia)
- increased number of certain white blood cells (eosinophilia)
- allergic reactions
- loss of appetite
- anxiety, dizziness, sleepiness, trembling, fainting
- spinning sensation
- impaired hearing, ringing in the ears (tinnitus)
- changes in the heart activity as measured in the ECG called “QT prolongation”
- feeling your heartbeat
- inflammation of the stomach, mouth and tongue
- wind, constipation, belching
- dry mouth
- failure of bile flow
- inflammation of the liver
- increase of liver enzymes in the blood
- itching, hives
- generally feeling unwell
- weakness
- chest pain
- chills
- tiredness
- dermatitis bullous (see “Serious side effects” above).

Frequency not known (frequency cannot be estimated from the available data)

- inflammation of the bowel, from mild to severe (see “Serious side effects” above)
- certain infections of the skin and underlying tissues (erysipelas)
- severe decrease of certain white blood cells (agranulocytosis)
- reduced number of blood platelets: signs may be unusual bruising and bleeding

- severe allergic reaction (anaphylactic reaction; see “Serious side effects” above)
- psychosis, a feeling of loss of identity
- a feeling of not being yourself, confusion
- depression, abnormal dreams, disorientation, hallucinations, mania
- fits
- changes in the senses of smell, loss of sense of smell and taste
- tingling or numbness
- deafness
- heart rhythm disturbances including life-threatening cases (ventricular arrhythmia, torsades de pointes; see “Serious side effects” above)
- prolongation of the blood clotting time
- acute inflammation of the pancreas (see “Serious side effects” above)
- discolouration of the teeth and tongue
- severe liver failure including life-threatening cases (see “Serious side effects” above)
- yellowing of your skin or whites of your eyes (jaundice)
- severe skin diseases with discomfort, redness, flaking and swelling (Stevens-Johnson syndrome, toxic epidermal necrolysis, DRESS, exanthematous pustulosis; see “Serious side effects” above)
- acne
- pain or weakness in muscles
- inflammation of the kidneys, kidney failure
- urine colour abnormal
- problems with your eyesight (blurred vision)
- impairment of vision.

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 national reporting system: HPRA

Pharmacovigilance; website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5 How to store Clorom

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

Do not use this medicine after the expiry date which is stated on the blister and carton after “EXP”. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 contains

The active substance is clarithromycin.

Each film-coated tablet contains 250 mg of clarithromycin.

Each film-coated tablet contains 500 mg of clarithromycin.

The other ingredients are:

- *core*: microcrystalline cellulose, croscarmellose sodium, magnesium stearate, cellulose powdered, silica colloidal anhydrous.
- *film-coating*: hypromellose, lactose monohydrate, titanium dioxide (E171), macrogol 4000.

What Clorom looks like and contents of the pack

White, oblong, convex, coated tablets, scored on both faces.

The film-coated tablets are packed in PVC/Aluminium blisters.

The blisters are inserted into carton boxes.

The tablet can be divided into equal doses.

250 mg film-coated tablets:

Pack sizes: 7, 8, 10, 12, 14, 15, 16, 20, 50, 60 or 100 film-coated tablets.

500 mg film-coated tablets:

Pack sizes: 7, 10, 12, 14, 15, 16, 20, 21, 30, 42, 50, 56, 60, 100 or 140 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers

Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.

Sandoz S.R.L. Str. Livezeni nr. 7A, RO-540472 Targu-Mures, Romania.

Rowa Pharmaceuticals Ltd., Newtown, Bantry, Co. Cork, Ireland.

Betapharm Arzneimittel GmbH, Wasserberg 11, 86441, Zusmarshausen, Germany.

LEK S. A., ul. Domaniewska 50C, 02-672 Warszawa, Poland.

LEK Pharmaceuticals d. d., Verovškova ulica 57, 1526 Ljubljana, Slovenia.

This medicine is authorised in the Member States of the European Economic Area under the following names:

Netherlands: Claritromycine Sandoz 250 mg, filmomhulde tabletten

Netherlands: Claritromycine Sandoz 500 mg, filmomhulde tabletten

Ireland: Clorom 250 mg Film-coated tablets

Ireland: Clorom 500 mg Film-coated tablets

Italy: CLARITROMICINA HEXAL 250 mg compresse rivestite con film

Italy: CLARITROMICINA HEXAL 500 mg compresse rivestite con film

This leaflet was last revised in 02/2024.