

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 to any of the other ingredients of this medicine listed in section 6,
- if you or someone in your family has a history of certain abnormal **heart rhythms** (ventricular arrhythmia, including torsades de pointes) or changes in the heart activity as measured in the ECG called “QT prolongation”,
- if you suffer from severe **liver** failure and **kidney** problems **at the same time**,
- if your **blood potassium** or **magnesium** level is low (hypokalaemia or hypomagnesaemia),
- if you are taking
  - **ticagrelor** (to prevent blood clotting)
  - **ranolazine** (used to treat angina pectoris)
  - **ergotamine, dihydroergotamine** (medicines to treat migraine),
  - **cisapride** (gastric medicine),
  - **pimozide** (antipsychotic),
  - **terfenadine, astemizole** (antiallergics)
  - **lovastatin, simvastatin** (medicines to lower cholesterol)
  - **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**,
- if your **blood magnesium level has previously been low**.

**Other medicines and Clorom**

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.

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

**Clorom may increase the effect of the following medicines:**

- Astemizole, terfenadine (antiallergics), pimozide (antipsychotic), cisapride (gastric medicine), ergotamine, dihydroergotamine (migraine medicine), lovastatin, simvastatin (medicines to lower cholesterol), ticagrelor (to prevent blood clotting), ranolazine (used to treat angina pectoris), colchicine (to treat gout) (see “Do not take Clorom”)
- Alprazolam, triazolam, midazolam (hypnotics)
- Digoxin, verapamil, amlodipine, diltiazem (heart medicines)
- Theophylline (antiasthmatic)
- Warfarin (blood thinning medicine)
- 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)
- Vinblastin (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 taking 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)

**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.

**Clorom contains lactose**

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 Clorom.

**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.

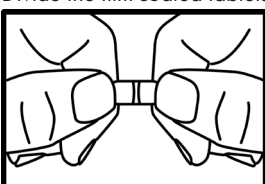
Take a glass of water with the medicine.

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.

Continued on the next page >>

#### 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 **heart beat** or irregular heart beat
- Inflammation of the pancreas, which causes **severe pain in the abdomen and back**.

#### **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

**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
- Spinning sensation
- Impaired hearing, ringing in the ears (tinnitus)
- Changes in the heart activity as measured in the ECG called "QT prolongation"
- Feeling your heart beat
- 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.

#### **Frequency not known**

- 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
- 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)
- Discoloration 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; see "Serious side effects" above)
- Acne
- Pain or weakness in muscles
- Inflammation of the kidneys, kidney failure
- Urine color abnormal.

#### **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](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@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.

*Clorom 250 mg Film-Coated Tablets:*

1 film-coated tablet contains 250 mg of clarithromycin.

*Clorom 500 mg Film-Coated Tablets:*

1 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 (E 171), macrogol 4000.

#### **What Clorom looks like and contents of the pack**

Film-coated tablet

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

The tablet can be divided into equal doses.

*Clorom 250 mg Film-Coated Tablets:*

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

*Clorom 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.

Salutas Pharma GmbH, Dieselstr. 5, 70839 Gerlingen, 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 57, 1526 Ljubljana, Slovenia.

#### **This medicinal product is authorised in the Member States of the EEA under the following names:**

|              |                                                          |
|--------------|----------------------------------------------------------|
| Germany:     | Clarithrobeta 250 mg Filmtabletten                       |
| Germany:     | Clarithrobeta 500 mg Filmtabletten                       |
| Netherlands: | Clarithromycine Sandoz 250 mg, filmomhulde tabletten     |
| Netherlands: | Clarithromycine 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 |
| Luxembourg:  | Clarithromycin HEXAL® 250 mg Filmtabletten               |
| Luxembourg:  | Clarithromycin HEXAL® 500 mg Filmtabletten               |

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