

Package leaflet: Information for the user:

Clarithromycin 250mg Film-coated Tablets Clarithromycin 500mg Film-coated Tablets

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 Clarithromycin Film-coated Tablets are and what they are used for
2. What you need to know before you take Clarithromycin Film-coated Tablets
3. How to take Clarithromycin Film-coated Tablets
4. Possible side effects
5. How to store Clarithromycin Film-coated Tablets
6. Contents of the pack and other information

1. What Clarithromycin Film-coated Tablets are and what they are used for

Clarithromycin is a macrolide antibiotic which is highly effective in the treatment of a variety of infections including:

- Throat and sinus infections
- Chest infections such as bronchitis and pneumonia
- Skin and soft tissue infections
- *Helicobacter pylori* infections associated with duodenal ulcers.

Clarithromycin film-coated tablets are indicated in adults and children 12 years and older.

2. What you need to know before you take clarithromycin film-coated tablets

Do not take Clarithromycin Film-coated Tablets if:

- you are allergic to clarithromycin, other macrolide antibiotics such as erythromycin or azithromycin, or any of the other ingredients of this medicine (listed in section 6)
- you have abnormally low levels of potassium in your blood (hypokalaemia)
- you have severe liver disorders combined with kidney disorders
- someone in your family has a history of heart rhythm disorders (ventricular cardiac arrhythmia, including torsades de pointes) or abnormality of electrocardiogram (ECG, electrical recording of the heart) called "long QT syndrome"
- you are taking:
 - medicines called terfenadine or astemizole (for hay fever or allergies) or cisapride (for stomach disorders) or pimozide (for mental health problems) as combining these drugs can sometimes cause serious disturbances in heart rhythm. Consult your doctor for advice on alternative medicines.
 - other medicines which are known to cause serious disturbances in heart rhythm
 - medicines called ergot alkaloid tablets (e.g. ergotamine or dihydroergotamine) or use ergotamine inhalers (for migraine)
 - lovastatin or simvastatin (treatments to lower cholesterol [a type of fat] in blood)
 - ticagrelor (for stroke or heart attack)
 - ranolazine (for chest pain)
 - colchicine (for gout)
 - oral midazolam (a sedative)

If any of the above applies to you, consult your doctor for advice on alternative medicines.

Warnings and precautions

Talk to your doctor or pharmacist before taking Clarithromycin Film-coated Tablets:

- if you have a liver or kidney disorder
- if you are resistant to other antibiotics such as clindamycin, lincosamin
- if you have heart problems (e.g. heart disease, heart failure, an unusually slow heart rate, or low levels of magnesium in the blood)
- if you have hypomagnesaemia (low blood magnesium)
- if you take anticoagulants, e.g. warfarin (medicines to thin your blood). Your prothrombin time should be monitored frequently
- if you take medicines, which can impair hearing, especially aminoglycosides (group of medicine to treat some infections). Your doctor should check your ability to hear, if necessary
- if you take medicines to lower your blood sugar. Their effect might be increased by Clarithromycin
- if you have pneumonia, as the causing bacteria (*Streptococcus pneumoniae*) might be resistant against clarithromycin
- if you have, or are prone to, fungal infections (e.g. thrush)
- if you are pregnant or breast feeding

If any of the above applies to you, consult your doctor before taking Clarithromycin Film-coated Tablets.

Stop taking Clarithromycin Film-coated Tablets and tell your doctor, if you:

- develop severe diarrhoea during or after treatment with Clarithromycin Film-coated Tablets. Medicines that prevent peristalsis (bowel movement) such as anti-diarrhoeal treatments should be avoided
- develop yellowing of the skin (jaundice), skin irritation, pale stools, dark urine, tender abdomen or loss of appetite. These may be signs that your liver may not be working properly.
- develop another infection.

Clarithromycin Film-coated tablets are not suitable for use in children under 12 years of age.

Other medicines and Clarithromycin Film-coated Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

You should not use Clarithromycin Film-coated Tablets if you are taking any one of the following medicines (see section **Do not take Clarithromycin Film-coated Tablets if**)

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

- ergotamine or dihydroergotamine (for migraine)
- lovastatin or simvastatin (treatments to lower cholesterol [a type of fat] in blood)
- ticagrelor (for stroke or heart attack)
- ranolazine (for chest pain)
- colchicine (for gout)
- quetiapine (for bipolar disorder and schizophrenia)
- oral midazolam (a sedative).

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

- digoxin (for heart failure)
- quinidine or disopyramide (for heartbeats disorders)
- intravenous or oromucosal midazolam (sedatives/sleeping pills)
- triazolam (sleeping pills)
- alprazolam (for anxiety)
- clobazam (for poor circulation)
- verapamil, amlodipine and diltiazem (medicine against high blood pressure)
- tolterodine (medicine to treat urinary incontinence)
- St. John's wort (herbal product used for depression)
- cyclosporin, tacrolimus or sirolimus (help prevent rejection after transplant)
- theophylline (used in patients with breathing difficulties such as asthma)
- efavirenz, nevirapine, ritonavir, etravirine, zidovudine, atazanavir or saquinavir (HIV treatments)
- rifampicin, rifabutin or rifapentine (antibiotics used in the treatment of certain bacterial infections)
- fluconazole, itraconazole (antifungal medicine)
- warfarin (blood thinner)
- atorvastatin, rosuvastatin (cholesterol-lowering drugs). Statins can cause rhabdomyolysis (a condition which causes the breakdown of muscle tissue which can result in kidney damage). Signs of myopathy (muscle pain or muscle weakness) should be monitored.
- omeprazole antacid (for heartburn or ulcers) unless your doctor has prescribed it for you to treat *Helicobacter pylori* infection associated with stomach or duodenal ulcers
- methylprednisolone (a corticosteroid)
- vinblastine (for treatment of cancer)
- phenytoin, carbamazepine, valproate or phenobarbital (for epilepsy)
- insulin or other diabetes medicines, e.g. pioglitazone, rosiglitazone, repaglinide and nateglinide (used to lower blood glucose levels)
- sildenafil, tadalafil and vardenafil (for impotence in adult males or for use in high blood pressure in the blood vessels of the lungs)
- aminoglycosides (a group of antibiotic to treat certain bacteria for example gentamicin, neomycin)
 - glycidazide or glimeperide (sulphonylureas used in the treatment of type II diabetes)
- quetiapine or other antipsychotic medicines
- other macrolide medicines
- lincosamin and clindamycin (lincosamides – a type of antibiotic)

Please tell your doctor if you are taking oral contraceptive pills and diarrhoea or vomiting occurs as you may need to take extra contraceptive precautions such as using a condom.

It may still be all right for you to be given Clarithromycin Film-coated tablets and your doctor will be able to decide what is suitable for you.

Clarithromycin Film-coated Tablets with food and drink

Clarithromycin Film-coated Tablets may be taken with or without 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 before taking this medicine as the safety of Clarithromycin Film-coated Tablets in pregnancy and breast-feeding is not known. Your doctor will decide if it is ok for you to take Clarithromycin Film-coated Tablets.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Clarithromycin Film-coated Tablets may cause dizziness, vertigo (spinning sensation), confusion or disorientation (not knowing where you are). If affected, you should not drive or operate machines.

3. How to take Clarithromycin Film-coated Tablets

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

Adults, older people and children over 12 years

For chest infections, throat or sinus infections and skin and soft tissue infections: The usual dose is 250 mg twice daily. This may be increased to 500 mg twice daily for severe infections.

For the treatment of *Helicobacter pylori* as part of a treatment for duodenal ulcers:

There are a number of effective treatment combinations available to treat *Helicobacter pylori* in which clarithromycin tablets are taken together with one or two other drugs.

These combinations include the following and are usually taken for 6 to 14 days:

- a) One Clarithromycin 500 mg tablet taken twice a day together with amoxicillin, 1000 mg taken twice a day plus lansoprazole, 30 mg twice a day.
- b) One Clarithromycin 500 mg tablet taken twice a day together with metronidazole, 400 mg taken twice a day plus lansoprazole, 30 mg twice a day.
- c) One Clarithromycin 500 mg tablet taken twice a day together with amoxicillin, 1000 mg taken twice a day or metronidazole, 400 mg taken twice a day plus omeprazole, 40 mg a day.
- d) One Clarithromycin 500 mg tablet taken twice a day together with amoxicillin, 1000 mg taken twice a day plus omeprazole, 20 mg taken once a day.

The treatment combination that you receive may differ slightly from the above. Your doctor will decide which treatment combination is the most suitable for you. If you are unsure which tablets you should be taking or how long you should be taking them for, please consult your doctor for advice.

Use in renal impairment

Patients with a severe kidney disorder may need a reduced dose and their treatment should not be longer than 14 days.

Clarithromycin 500 mg Film-coated Tablets can be divided into equal doses. Clarithromycin Film-coated tablets should be swallowed with at least half a glass of water. Clarithromycin film-coated Tablets may be taken with or without food.

Clarithromycin Film-coated Tablets are not suitable for children less than 12 years of age. They should receive Clarithromycin granules for oral suspension.

Duration of treatment

The usual length of treatment is 6 to 14 days.

If you take more Clarithromycin Film-coated Tablets than you should

If you accidentally take more Clarithromycin Film-coated Tablets in one day than your doctor has told you to, or if a child accidentally swallows some tablets, contact your doctor, pharmacist or nearest hospital emergency department immediately. An overdose of Clarithromycin is likely to cause vomiting and stomach pains.

If you forget to take Clarithromycin Film-coated Tablets

If you miss, a dose take it as soon as possible. However if it is nearly time for your next dose, skip the missed dose and carry on as before. Do not take a double dose to make up for a forgotten dose.

If you stop taking Clarithromycin Film-coated Tablets

Do not stop taking Clarithromycin Film-coated Tablets, even if 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.

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

If you suffer from any of the following at any time during your treatment stop taking your tablets and contact your doctor immediately.

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

- any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching. This is a sign that you may have developed an allergic reaction.

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

- contact a doctor immediately if you experience a serious skin reaction; a red, scaly rash with bumps under the skin and blisters (exanthematous pustulosis)
- severe form of skin rash with flushing, fever, blisters or ulcers (Stevens Johnson syndrome), severe rash involving reddening, peeling and swelling of the skin that resembles severe burns (toxic epidermal necrolysis)
- rash fever, abnormal blood count and inflammation of internal organs. These may be symptoms of drug reaction with eosinophilia and systemic symptoms (DRESS).
- severe or prolonged diarrhoea, which may have blood or mucus in it. Diarrhoea may occur over two months after treatment with clarithromycin, in which case you should still contact your doctor (see also **Warnings and precautions**).
- jaundice (yellowing of the skin or eyes), skin irritation, pale stools, dark urine, tender abdomen or loss of appetite. These may be signs that your liver may not be working properly.

Tell your doctor immediately or go to the casualty department at your nearest hospital if any of the following happens:

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

- abnormal liver test results

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

- heart attack, dangerously fast heartbeat, ECG changes, extra heart beats, palpitations
- blood clot in the lungs which causes chest pain and breathlessness

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

- changes in heartbeat rhythm (torsades de points), increased heart rate (tachycardia)
- inflammation of the pancreas (combined with severe pain in the upper abdominal region radiating to the back, along with nausea and vomiting)
- inflammation of kidneys (combined with blood in the urine, fever, and pain in the sides)
- hypoglycaemia (abnormally low blood sugar indicated by feeling hungry, sweating, dizziness, heart palpitation) particularly after taking anti-diabetic medicine
- muscle weakness, tenderness or pain and particularly, if at the same time, you feel unwell or have a high temperature it may be caused by an abnormal muscle breakdown, which can lead to kidney problems (rhabdomyolysis)

Other side effects

Tell your doctor as soon as possible if any of the following develops:

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

- rash
- sleeplessness (insomnia)
- headache
- feeling sick (nausea), vomiting, stomach pain, indigestion, diarrhoea
- change in the sense of taste, altered taste (for example metallic or bitter taste)
- increased sweating (hyperhidrosis)
- widening of blood vessels.

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

- inflammation of the skin with blisters (dermatitis bullous), itching of the skin, skin rash and hives (urticaria), rash characterized by a flat, red area on the skin that is covered with small confluent bumps (rash maculo-papular)
- hot, tender and red skin, sometimes with fever and chills (cellulitis)
- oral or vaginal 'thrush' (a fungal infection)
- mild to severe nausea, vomiting, cramps, diarrhoea. These symptoms may be due to inflammation of the stomach and intestines, usually caused by a virus
- a burning sensation in the chest rising up to the throat, also known as heartburn
- inflammation of the food pipe (oesophagitis), stomach (gastritis), in the mouth or the tongue
- constipation, dry mouth, winds, abdominal distension, belching
- bile disorder (cholestasis)
- fever, generally feeling unwell, feeling of

- weakness, chest pain, chills, tiredness, pain in muscles, muscle stiffness, muscle spasms or loss of muscle tissue. If you suffer from myasthenia gravis (a condition in which the muscles become weak and tired easily) clarithromycin may worsen these symptoms
- decreased appetite, loss of appetite (anorexia)
- anxiety, screaming, nervousness
- loss of consciousness, uncontrollable twitching, jerking or writhing movements (dyskinesia), dizziness, drowsiness, tremors or shaking
- hearing impaired
- spinning sensation (vertigo), ringing in the ears (tinnitus)
- frequent infections such as fever, severe chills, sore throat or mouth ulcers. These symptoms may be due to low count of white blood cells
- increase in some white blood cells
- increase platelet count (thrombocytopenia)
- raised blood urea nitrogen or creatinine (waste products)
- changed blood levels of albumin, globulin and diverse enzymes (alkaline phosphatase, lactate dehydrogenase)
- breathlessness, wheezing, a cough sometimes brought on by exercise, and a feeling of tightness in the chest (asthma)
- nose bleed
- pain in the rectum
- decrease in neutrophils (neutropenia)

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

- inflammation of the colon
- bacterial infections of the skin (erysipelas)
- abnormal urine colour
- tongue discoloration, tooth discoloration
- severely reduced kidney function (renal failure)
- deafness
- depression, hallucinations, abnormal thoughts (psychosis), not knowing where you are (disorientation), out of body feeling (depersonalization), bad dreams, confusion and mania (feeling of elation or over-excitement)
- numbness and tingling in arms and legs (paraesthesia)
- convulsions (fits)
- loss of taste functions of the tongue (ageusia)
- change in the sense of smell (parosmia), inability to perceive smells (anosmia)
- abnormally low counts of blood platelets (which may cause bruising of the skin or increased tendency to bleed)
- acne
- loss of blood (haemorrhage),
- long bleeding and blood clotting time

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 HPRP 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 Clarithromycin Film-coated Tablets

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 carton after "EXP". The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions. Store in the original package in order to protect from moisture.

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 Clarithromycin Film-coated Tablets contain

Each film-coated tablet contains clarithromycin 250mg or 500mg.

The other ingredients are microcrystalline cellulose, croscarmellose sodium, povidone, magnesium stearate, talc, colloidal anhydrous silica, stearic acid and the coating material Opadry 20H 52875 containing hypromellose, hydroxypropylcellulose, propylene glycol, vanillin, titanium dioxide, talc and quinoline yellow lake (E104)

What Clarithromycin Film-coated Tablets look like and contents of the pack

Clarithromycin 250mg Film-coated Tablets are light yellow, oval, biconvex film coated tablets embossed with 'C1' on one side.

Clarithromycin 500mg Film-coated Tablets are light yellow, oval, biconvex film coated tablets with 'C' and '2' embossed on either side of the breakline on one side and notched on both sides. The tablet can be divided into equal doses.

Clarithromycin Film-coated Tablets are available in blister strips of 1, 2, 10, 12, 14, 15, 20, 21, 30, 42, 50, 56 or 100 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Sun Pharmaceutical Industries Europe B.V., Polarisavenue 87, 2132 JH, Hoofddorp, The Netherlands

Manufacturer

Terapia S.A., 124 Fabricii Street, 400 632 Cluj-Napoca, Romania

Sun Pharmaceutical Industries Europe B.V., Polarisavenue 87, 2132 JH, Hoofddorp, The Netherlands

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

- Ireland:** Clarithromycin 250mg, 500mg Film-coated Tablets
- Italy:** Claritromicina Ranbaxy Italia 250mg, 500mg compresse rivestite con film
- Lithuania:** Klabax 250mg, 500mg plėvele dengtos tabletės
- Poland:** Klabax 250mg, 500mg tabletki powlekane
- UK:** Clarithromycin 250mg, 500mg Film-coated tablets

This leaflet was last revised in: February 2018