

Package leaflet: Information for the user
Clarithromycin 500 mg 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

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

Clarithromycin Film-Coated Tablets contains the active ingredient clarithromycin, which is an macrolide antibiotic which stop the growth of bacteria which cause infections.

Clarithromycin Film-Coated Tablets is indicated for use in adults and adolescents over 12 years of age for the treatment of infections caused by micro-organisms sensitive to clarithromycin. These infections include:

- Upper respiratory tract infections (e.g. pharyngitis, sinusitis)
- Lower respiratory tract infections (e.g. bronchitis, pneumonia)
- Acute otitis media
- Skin and soft tissue infections (e.g. impetigo, folliculitis, cellulitis, abscesses)
- Disseminated or localised mycobacterial infections

In HIV-infected patients (CD4 cell count $\leq 100/\text{mm}^3$), Clarithromycin is indicated for the prevention of disseminated infections caused by the *Mycobacterium avium* (MAC) complex.

In patients with duodenal ulceration and diagnostically confirmed *Helicobacter pylori* infection, clarithromycin treatment is recommended simultaneously with preparations that suppress gastric acid secretion and other antibiotics.

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 are taking ergot alkaloids, such as ergotamine or dihydroergotamine (medicines used, among others, to treat migraines) or oral midazolam (a medicine used to treat anxiety and insomnia).

- you are taking medicines which may cause serious disturbances in heart
- you are taking astemizole or terfenadine (medicines used to treat allergy), cisapride or domperidone (a medicine used to treat gastrointestinal tract disorders), pimozide (a medicine used to treat mental disorders), because they may cause serious disturbances in heart rhythm when taken together with clarithromycin.
- you are taking ticagrelor (a medicine that inhibits platelets aggregation) or ranolazine (a cardiac medicine).
- you have been diagnosed with low level of potassium or magnesium in the blood (hypokalaemia or hypomagnesaemia).
- you are taking lovastatin or simvastatin (statin medicines used to lower blood cholesterol).
- you have been diagnosed with severe liver failure with concurrent kidney failure.
- you have or anyone in your family has had a history of heart rhythm disturbances (ventricular cardiac arrhythmias, including *torsades de pointes*) or abnormal electrocardiogram results (ECG, measurement of the electrical activity of the heart) called “QT interval prolongation syndrome”.
- you are taking colchicine (a medicine used to treat gout).
- you are taking medicine containing lomitapide.

Warnings and precautions

Talk to your doctor or pharmacist before you start taking Clarithromycin Film-Coated Tablets:

- if you are pregnant or you think that you may be pregnant
- if you have a liver or kidney disorder
- if you have been diagnosed with coronary artery disease, severe heart failure or slowed heart rate
- if you are taking any of the medicines listed under section “Other medicines and Clarithromycin Film-Coated Tablets ”

If you experience any of the situations described below while taking Clarithromycin Film-Coated Tablets, you should tell your doctor about it.

- Severe hypersensitivity reactions, such as maculopapular rash, urticaria, ecchymosis, swelling of the larynx, bronchospasm. **Immediately** report to a doctor who will introduce appropriate treatment.
- Diarrhoea, especially acute or prolonged. Talk to your doctor as soon as possible. If necessary, the doctor will prescribe appropriate treatment. Do not use anti-diarrheal medicines.
- Symptoms indicating hepatic dysfunction, such as lack of appetite, jaundice, dark urine colour, pruritus or painful stomach. Stop treatment and report to the doctor.
- New infection (superinfection) with clarithromycin-resistant bacteria or fungi, especially during prolonged antibiotic use. The doctor will prescribe appropriate treatment.

Moreover, while taking Clarithromycin Film-Coated Tablets you may experience:

- cross-resistance of bacteria (clarithromycin-resistant bacteria may be also resistant to other macrolide antibiotics as well as lincomycin and clindamycin);
- drug-resistance of bacteria (e.g. the treatment of *Helicobacter pylori* infection may lead to the occurrence of drug-resistant microorganisms).

Other medicines and Clarithromycin Film-Coated Tablets

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

You must inform your doctor, if you are taking one of the following medicines, as it is contraindicated to use them with Clarithromycin Film-Coated Tablets:

- ergot alkaloids, such as ergotamine or dihydroergotamine (medicines used, among others, to treat migraines)
- astemizole or terfenadine (medicines used to treat allergy)
- cisapride or domperidone (a medicine used to treat gastrointestinal tract disorders)
- pimozide (a medicine used to treat mental disorders)
- ticagrelor, ranolazine (a medicine used to treat heart and circulatory diseases)
- colchicine (a medicine used to treat gout)
- statins – lovastatin, simvastatin (medicines used to lower blood cholesterol)
- midazolam administered orally (a medicine used to treat anxiety or insomnia)

Tell your doctor if you are taking any of the following medicines, as it is necessary to take special care while using them with Clarithromycin Film-Coated Tablets:

- rifampicin, rifapentine, rifabutin (antibiotics used to treat tuberculosis)
- fluconazole, itraconazole (antifungal medicines)
- atazanavir, efavirenz, etravirine, nevirapine, ritonavir, saquinavir, zidovudine (used to treat HIV infection)
- digoxin, quinidine, disopyramide, verapamil, amlodipine, diltiazem (used to treat heart disturbances or arterial hypertension)
- alprazolam, triazolam, midazolam administered intravenously or oromucosally (medicines used to treat anxiety or insomnia)
- warfarin or any other anticoagulant e.g. dabigatran, rivaroxaban, apixaban
- quetiapine or another atypical antipsychotic drug
- carbamazepine, valproate, phenytoin (antiepileptic drugs)
- methylprednisolone (an anti-inflammatory medicine)
- omeprazole (a medicine reducing the secretion of gastric acid)
- cilostazol (a medicine used to treat intermittent claudication which manifests as muscle pain of lower extremities during effort resolving after short rest)
- cyclosporine, tacrolimus, sirolimus (medicines used, among others, after transplants)
- sildenafil, tadalafil, vardenafil (medicines used to treat erectile dysfunction)
- ibrutinib or vinblastine (medicines used in cancer chemotherapy)
- theophylline (a medicine used to treat asthma)
- tolterodine (a medicine used to treat urinary incontinence)
- phenobarbital (an anti-seizure medicine)
- St. John's wort (a herbal medicine used to treat mild depression)
- sulfonyleurea, nateglinide, repaglinide, insulin (medicines used in diabetes).

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 in pregnancy and breast-feeding is not known. Clarithromycin Film-Coated Tablets may only be used during pregnancy when in the opinion of the physician the benefits for the mother outweigh the potential risk for the foetus.

Clarithromycin is excreted in mother's milk, so breastfeeding women should take special care when taking Clarithromycin Film-Coated Tablets.

Driving and using machines

This medicine may cause dizziness, vertigo, confusion and disorientation, which can affect the ability to drive and use machines. If affected, you should not drive or operate machines.

Clarithromycin Film-Coated Tablets contain sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially “sodium-free”.

3. How to take Clarithromycin Film-Coated Tablets

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

Medicine for oral use.

Swallow the tablet whole with water. Do not chew or suck the tablet.

The tablets may be taken with or without food.

Respiratory tract, skin and soft tissues infections, acute otitis media

Adults

In case of severe infections - one 500 mg tablet twice daily (every 12 hours).

The treatment usually takes from 5 to 14 days, excluding pneumonia and sinusitis when the treatment takes from 6 to 14 days.

Adolescents older than 12 years

Dosing as for adults.

Children aged 12 years and younger

It is recommended to use Clarithromycin Film-Coated Tablets in the form of an oral suspension.

Patients with renal impairment

The doctor may recommend to decrease the medicine dose by half, which means taking one 250 mg tablet once daily.

In the case of severe infections – one 250 mg tablet twice daily.

In this case is recommended to use Clarithromycin Film-Coated Tablets containing 250 mg of clarithromycin per tablet.

The treatment does not take longer than 14 days.

Infections caused by mycobacteria

Recommended dose in adults: one 500 mg tablet twice daily.

The treatment of a diffuse infection caused by the *Mycobacterium avium* complex (MAC) in patients with AIDS should be continued as per the doctor’s recommendations. Clarithromycin Film-Coated Tablets should be used in combination with other medicines against *Mycobacterium*.

The treatment of other, non-tuberculosis, mycobacteria infections should be continued as per the doctor’s recommendations.

Prevention of MAC infections

Recommended dose in adults: one 500 mg tablet twice daily.

Helicobacter pylori infections

Patients with peptic ulcer or duodenal ulcer caused by *Helicobacter pylori* infection may receive 500 mg clarithromycin twice daily for 7 to 14 days, in combination with an additional adequate antimicrobial therapy and proton pump inhibitors, as per the national and international recommendations on *Helicobacter pylori* elimination.

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

If you take more than the recommended dose of Clarithromycin Film-Coated Tablets contact your doctor or pharmacist immediately.

Taking more Clarithromycin Film-Coated Tablets than the dose recommended by your doctor may cause gastrointestinal tract symptoms (vomiting, stomach pain).

If you forget to take Clarithromycin Film-Coated Tablets

If you miss a dose, take it as soon as possible, and take another dose at the specified time.

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

If you stop taking Clarithromycin Film-Coated Tablets

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

Do not stop treatment, even if you feel better and the symptoms resolve after several days of taking the medicine.

4. Possible side effects

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

If you experience any of the following side effects anytime during the treatment, you **must stop taking** Clarithromycin Film-Coated Tablets and contact a doctor immediately:

- anaphylactic shock - acute, life-threatening allergic reaction, manifesting among others in confusion, pale skin, decreased blood pressure, sweating, low output of urine, accelerated breathing, weakness and fainting
- allergic reactions: rash (very common), itching, hives (uncommon), angioedema of the face, tongue, lips, eyes and pharynx, difficulties in breathing
- severe skin reactions:
 - acute generalized exanthematous pustulosis – red, exfoliating rash with nodules under the skin and blisters
 - erythema multiforme with blisters (Stevens-Johnson syndrome) manifesting in the form of sudden fever and pustules, which resolve quickly and spontaneously after stopping the medicine; serious disease manifesting in blisters and erosions of the skin, oral cavity, eyes and sexual organs, fever and joint pain
 - toxic epidermal necrolysis (Lyell's syndrome) – severe disease with rapid course manifesting in huge, cracking blisters formed under the epidermis, extensive skin erosions, sloughing of the epidermis in large sheets and fever
 - DRESS syndrome – severe (life-threatening) drug-induced rash with increased eosinophils count and internal organ involvement
- severe or prolonged diarrhoea, possibly with some blood or sludge in the stools (pseudomembranous colitis) Diarrhoea may occur even two months after the end of clarithromycin treatment. If this is the case, you should also contact a doctor.
- yellow skin (jaundice), skin irritation, pale stools, dark urine, tender abdomen or lack of appetite. These may be the symptoms of liver failure, cholestasis (increase of bile products in the blood), hepatitis (uncommon).

They occur with unknown frequency, unless indicated otherwise.

Other side effects

The following side effects (occur in 1 to 10 patients out of 100) were **often** reported in clinical studies and in post-marketing experience with clarithromycin:

- insomnia
- taste disturbances, headache
- diarrhoea, vomiting, indigestion, nausea, abdominal pain
- abnormal liver function results
- excessive sweating

Uncommon side effects (occur in 1 to 10 patients in 1000):

- candidiasis (fungal infections), vaginal infection
- decrease in white blood cells, decrease in neutrophils and increase of eosinophils
- anorexia, decreased appetite
- restlessness
- dizziness, sleepiness, shaking
- balance disorder, hearing loss, ringing in the ears
- palpitations, ECG trace changes (QT interval prolongation)
- inflammation of the stomach, inflammation of the mouth, inflammation of the tongue, bloating, constipation, dry mouth, burping, wind
- increased liver enzymes activity: alanine aminotransferase, increased aspartate aminotransferase activity, increased gamma-glutamyl transferase activity
- malaise, asthenia (weakness, lack of energy), chest pain, chills, fatigue
- increased blood enzyme activity: alkaline phosphatase and lactate dehydrogenase

The frequency of the side effects listed below is **not known** (the frequency cannot be estimated from the available data); they were reported in post-marketing experience with Clarithromycin Film-Coated Tablets in the form of tablets and suspension:

- erysipelas
- agranulocytosis (reduction in the number of white blood cells in the blood), thrombocytopenia (decreased platelet count)
- acne
- psychotic disorders, confusional state, depersonalization, depression, disorientation, hallucinations, abnormal dreams, mania
- seizures, lack of taste, change in the sense of smell (parosmia), loss of smell, paraesthesia (numbness, tingling)
- deafness
- type of heart rhythm disorder (*Torsade de pointes*, ventricular tachycardia, ventricular fibrillation)
- haemorrhage
- acute inflammation of the pancreas, discolouration of the tongue or teeth
- myopathy (a muscle disease involving muscle strength reduction)
- renal failure, interstitial nephritis
- change in diagnostic test results (increased international normalized ratio [INR], prolonged prothrombin time, abnormal urine colour)

Immunosuppressed patients

Apart from the symptoms related to the disease course, the following side effects were observed in adult immunosuppressed patients:

- nausea, vomiting, altered taste, constipation, abdominal pain, diarrhoea, bloating with passing winds, dry mouth

- headache, hearing disorders
- rash
- dyspnoea, insomnia
- abnormal laboratory test results: increased aspartate aminotransferase activity (AspAT) and alanine aminotransferase (AlAT), increased blood urea nitrogen and decreased platelet count and white blood cell count

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 HPRC 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 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 and blister 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 contains

Each film-coated tablet contains clarithromycin 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 (E 104)

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

Clarithromycin 500mg Film-coated Tablets are light yellow, oval, biconvex film coated tablets with 'C' and '2' embossed on either side of a 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, 10, 1x10, 14, 1x14, 20, 21, 30, 42, 50 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

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

Ireland: Clarithromycin 500mg Film-Coated Tablets

Italy: Claritromicina Sun Pharma 500mg compresse rivestite con film

Lithuania: Klabax 500mg plėvele dengtos tabletės

Poland: Klabax 500mg tabletki powlekane

United Kingdom (Northern Ireland): Clarithromycin 500mg Film-Coated Tablets

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