

PACKAGE LEAFLET

Package leaflet: Information for the user

Clarithromycin Teva 250 mg film-coated tablets Clarithromycin Teva 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 Clarithromycin Teva is and what it is used for
2. What you need to know before you take Clarithromycin Teva
3. How to take Clarithromycin Teva
4. Possible side effects
5. How to store Clarithromycin Teva
6. Contents of the pack and other information

1. What Clarithromycin Teva is and what it is used for

Clarithromycin Teva belongs to a group of drugs called macrolide antibiotics.

Clarithromycin Teva is used in the treatment of the following infections:

- bronchitis and pneumonia
- throat and sinus infections: sinusitis and pharyngitis
- skin and soft tissue infections
- *Helicobacter pylori* infection associated with duodenal ulcer.

2. What you need to know before you take Clarithromycin Teva

Do not take Clarithromycin Teva

- if you are allergic to clarithromycin, to other macrolide antibiotics (e.g. erythromycin, azithromycin) or to any of the other ingredients of this medicine (listed in section 6).
- if you are taking any of the following medicines:
 - astemizole or terfenadine (for hay fever or allergies), cisapride or domperidone (for stomach disorders) or pimozide (to treat certain psychiatric diseases) as taking these medicines with Clarithromycin Teva can 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
 - lomitapide (used to lower cholesterol)
 - ticagrelor (a blood-thinning medicine)
 - ivabradine or ranolazine (used to treat angina pectoris)
 - ergot alkaloids, for example ergotamine or dihydroergotamine tablets or if you are using ergotamine inhalers for migraine. Consult your doctor for advice on alternative medicines.
 - simvastatin or lovastatin (used to lower increased blood fats such as cholesterol and triglycerides)
 - colchicine (used to treat gout)
 - oral midazolam (for anxiety or to help sleep)

- if you or someone in your family has a history of heart rhythm disorders (ventricular cardiac arrhythmia, including torsade de pointes) or abnormality of electrocardiogram (ECG, electrical recording of the heart) called “long QT syndrome”
- if you have abnormally low levels of potassium or magnesium in your blood (hypokalaemia or hypomagnesaemia).
- if you suffer from severe liver disease and kidney disease at the same time.

Warnings and precautions

Talk to your doctor or pharmacist before taking Clarithromycin Teva if you

- have liver problems
- have kidney problems
- have certain heart problems (coronary heart disease, severe cardiac insufficiency, abnormal heart rhythms or clinically relevant slow heart beat)
- have, or are prone to, fungal infections (e.g. thrush)
- are using medicines that lower your blood sugar (oral hypoglycaemic agents or insulin)
- need to have intravenous or oromucosal (absorbed in the mouth) midazolam.
- are taking other macrolide antibiotics, as well as lincomycin and clindamycin
- have repeated infections with bacteria or fungi. Consult your doctor for advice
- are pregnant or breast feeding.

If you develop any symptoms of **liver dysfunction** such as **anorexia (loss of appetite), yellowing of the skin or whites of the eyes, dark urine, itching or tender abdomen, stop taking Clarithromycin Teva and tell your doctor immediately.**

If you develop **severe or prolonged diarrhoea** during or after receiving Clarithromycin Teva, **tell your doctor immediately**, as this could be a symptom of more serious conditions such as pseudomembranous colitis or clostridium difficile associated diarrhoea.

If you are having an allergic reaction (e.g. **difficulty in breathing, dizziness, swelling of the face or throat, rash, wheals, blistering**), **stop taking clarithromycin and contact a doctor immediately.**

Clarithromycin therapy in *Helicobacter pylori* infections can lead to selection of bacteria against which clarithromycin is ineffective.

Long term use of antibiotics can result in renewed infection (superinfection) with non-sensitive organisms. The symptoms of possible secondary infection are fever and worsening of your general condition. If a superinfection occurs, contact to your doctor immediately.

Children

This medicine is not suitable for use in children below 12 years of age (weighing less than 30 kg). Other pharmaceutical forms are more suitable for those patients.

Other medicines and Clarithromycin Teva

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

Do not take Clarithromycin Teva if you are taking

- ergotamine or dihydroergotamine (used to treat migraines)
- terfenadine or astemizole (used to treat hay fever and other allergies)
- pimozone (used to treat mental disorders)
- cisapride or domperidone (used to treat stomach problems)
- simvastatin, lovastatin or lomitapide (used to lower cholesterol)
- colchicine (used to treat gout)
- ticagrelor (a blood-thinning drug)
- ivabradine or ranolazine (used to treat angina pectoris)
- oral midazolam (for anxiety or to help sleep).

(see also above ‘Do not take Clarithromycin Teva’)

Talk to your doctor if you are taking any of the following

- warfarin or any other anticoagulant e.g. dabigatran, rivaroxaban, apixaban, edoxaban(used to thin your blood)
- disopyramide or quinidine (used to treat an abnormal heart beat)
- digoxin (used to treat heart failure)
- carbamazepine, valproate, phenobarbital or phenytoin (used to treat epilepsy or bipolar disorder (manic depression))
- theophylline (used to treat asthma)
- benzodiazepines used as medicines that make you sleepy, e.g. midazolam, triazolam or alprazolam
- rifabutin, rifampicin, rifapentine or aminoglycosides (e.g. gentamicin) (used to treat some infections)
- ciclosporin, tacrolimus or sirolimus (used following organ transplant).
- atorvastatin or rosuvastatin (used to lower cholesterol)
- efavirenz, nevirapine, atazanavir, saquinavir, ritonavir, zidovudine or etravirine (used to treat HIV infected patients)
- St John's Wort (a herbal product used to treat depression).
- fluconazole, itraconazole or ketoconazole (used to treat fungal infections)
- sildenafil, tadalafil or vardenafil (used to treat sexual dysfunction in men, and high blood pressure).
- omeprazole (for stomach disorders)
- insulin, glibenclamide, repaglinide or nateglinide (used to treat diabetes)
- cilostazol (used to treat cramp-like pain in the legs).
- eletriptan (used to treat migraines)
- aprepitant (used to treat nausea and vomiting during chemotherapy)
- halofantrine (used to treat malaria)
- quetiapine or ziprasidone (used to treat mental disorders)
- methylprednisolone (a corticosteroid used to treat inflammation)
- ibrutinib or vinblastine (for treatment of cancer)
- verapamil, amlodipine or diltiazem (used to treat heart problems)
- tolterodine (medicine to treat an overactive bladder).
- 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).

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

Clarithromycin Teva should not be given to pregnant or breast-feeding mothers unless the benefits to the mother outweigh the risks to the baby. Small amounts of clarithromycin can pass into breast milk.

Driving and using machines

Clarithromycin Teva may make you feel sleepy, dizzy or confused. DO NOT drive or operate machinery if you are affected.

Clarithromycin Teva contains tartrazine lake, allura red lake and sodium

This medicine contains tartrazine lake (E102) and allura red lake (E129) which may cause allergic reactions.

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

3. How to take Clarithromycin Teva

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

The tablets should be swallowed preferably with a glass of water. You can take Clarithromycin Teva either with or without food, whichever you prefer.

The recommended dosage instructions are given below:

Adults including the elderly and children over 12 years old

For chest infections, throat or sinus infections and skin and soft tissue infections

The recommended dose is 250 mg twice a day. Your doctor may increase the dose to 500 mg twice a day in severe infections. The usual duration of treatment is 6 to 14 days.

For the treatment of *Helicobacter pylori* infection associated with duodenal ulcers

Clarithromycin should be taken in a dose of 500 mg twice daily in combination with other medicines to treat *Helicobacter pylori*.

Your doctor will decide on the best treatment combination for you. If you are at all unsure as to which medicine to take and when to take the medicine you must speak to your doctor.

Patients with liver or kidney problems

If you have liver or severe kidney problems, your doctor may need to reduce your dose. Clarithromycin Teva should not be taken for more than 14 days if you have these problems.

Children under 12 years old

Clarithromycin is not recommended for use in children under 12 years of age.

If you take more Clarithromycin Teva than you should

If you (or someone else) swallow a lot of the tablets all together, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately.

An overdose is likely to cause vomiting and stomach pains.

Please take this leaflet, any remaining tablets and the container with you to the hospital or doctor so that they know which tablets were consumed.

If you forget to take Clarithromycin Teva

If you forget to take a tablet, take one as soon as you remember, unless it is nearly time to take the next one.

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

If you stop taking Clarithromycin Teva

DO NOT stop taking your medicine because you are feeling better. It is important that you complete your prescribed course of treatment, otherwise the problem may come back and this medicine may be less effective next time.

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.

If you notice any of the following serious side effects, stop taking Clarithromycin Teva and contact a doctor immediately:

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

- **rash, difficulty breathing, fainting or swelling of the face and throat.** This is a sign that you may have developed an allergic reaction.

Not known (frequency cannot be estimated from the available data)

- **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.

- **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.
- **severe pain in the abdomen and back** caused by inflammation of the pancreas.
- **severe acute allergic reactions** which causes difficulty in breathing or dizziness (anaphylactic reactions)
- **swelling of face and/or throat** (angioedema)
- **severe skin reactions such as blistering of the skin, mouth, lips, eyes and genitals** (symptoms of a rare allergic reaction called Stevens-Johnson syndrome/toxic epidermal necrolysis).
- **severe skin reaction such as a red, scaly rash with bumps under the skin and blisters** (exanthematous pustulosis)
- **severe skin reaction which causes severe illness with rash, fever and inflammation of internal organs** (DRESS)
- **a life threatening irregular heart beat** (torsade de pointes).

Other side effects

Common (may affect up to 1 in 10 people)

- difficulty sleeping (insomnia)
- changes in sense of taste
- headache
- widening of blood vessels
- stomach problems such as feeling sick, vomiting, abdominal pain, indigestion, diarrhoea
- abnormal liver function (seen in blood results)
- skin rash
- increased sweating.

Uncommon (may affect up to 1 in 100 people)

- infections such as infections of the stomach and intestine, inflammation of the skin caused by infections, oral or vaginal 'thrush' (a fungal infection), vaginal bacterial infection
- low levels of white blood cells (neutropenia and leukopenia) and other white blood cell disorders (eosinophilia)
- loss of appetite, decreased appetite
- anxiety, nervousness
- fainting, dizziness, drowsiness, tremor, involuntary movements of the tongue, face, lips or limbs.
- spinning sensation (vertigo), ringing in the ears (tinnitus), hearing impairment.
- fast, pounding heart (palpitations), changes in heart rhythm or heart stopping.
- breathing problems (asthma), nosebleed.
- blood clot in the lungs
- stomach problems such as bloating, constipation, burping (eructation), wind (flatulence), heartburn.
- inflammation of the lining of the stomach (gastritis) or oesophagus (the tube connecting your mouth with your stomach), pain in the rectum (proctalgia), inflammation of the mouth or tongue, dry mouth.
- increase in liver enzymes, liver problems such as hepatitis (inflammation of the liver) or disturbance of bile flow (cholestasis) which may cause yellowing of the skin (jaundice), pale stools or dark urine.
- itching, hives
- red areas on the skin covered with small confluent bumps (maculopapular rash)
- blisters on the skin which are filled with fluid (dermatitis bullous)
- stiffness, muscle pain, muscle cramps
- kidney problems such as raised levels of protein normally excreted by the kidneys or raised levels of kidney enzymes.
- fever, chills, weakness, fatigue, chest pain or general feeling of discomfort
- abnormal blood test results.

Not known (frequency cannot be estimated from the available data)

- bacterial skin infections (erysipelas)

- severe reduction of certain white blood cells (agranulocytosis); symptoms may include high fever, chills, sore throat, difficulty swallowing and inflammation of the mouth, nose, throat and genital or anal area.
- reduction of platelets in the blood (thrombocytopenia); symptoms may include increased bleeding tendency and petechiae (punctate bleeding in the skin and mucous membranes)
- psychotic disorder, confusion, change in sense of reality, depression, disorientation, hallucinations (seeing things), abnormal dreams
- feeling elated or overexcited, which causes unusual behaviour (mania)
- convulsion (fits)
- changes or loss in sense of taste and/or smell
- paraesthesia (tingling and burning sensation in the skin, numbness, ‘pins and needles’ sensation)
- deafness
- increased heartbeat, ventricular fibrillation (uncoordinated contraction of the heart muscle)
- bleeding
- discolouration of the tongue or teeth
- acne
- muscle weakness (myopathy), breakdown of muscle tissue. (rhabdomyolysis); if you suffer from myasthenia gravis (a condition in which the muscles become weak and tire easily), Clarithromycin may worsen these symptoms
- inflammation of the kidney or an inability of the kidney to function properly (you may notice tiredness, swelling or puffiness in the face, abdomen, thighs or ankles or problems with urination), or kidney failure
- abnormal colour of the urine
- blood clotting time increased (increased INR and prothrombin time).

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 Teva

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

Do not store above 25°C.

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.

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 Teva contains

- The active substance is clarithromycin. Each film-coated tablet contains 250 mg or 500 mg clarithromycin.
- The other ingredients are sodium starch glycolate, microcrystalline cellulose, povidone (PVP K-30), magnesium hydroxide, croscarmellose sodium, anhydrous colloidal silica, stearic acid, magnesium stearate, hypromellose (E464), titanium dioxide (E171), macrogol 400, tartrazine lake (E102), allura red AC lake (E129), indigo carmine lake (E132) and vanillin.

What Clarithromycin Teva looks like and contents of the pack

Clarithromycin Teva 250 mg is a yellow, oval shaped film-coated tablet marked with “93” on one side and “7157” on the other.

Clarithromycin Teva 500 mg is a light yellow, oval shaped film-coated tablet marked with “93” on one side and “7158” on the other.

Clarithromycin Teva 250 mg is available in pack sizes of 8, 10, 12, 14, 14 calendar pack, 16, 20, 30, 100 and 120 film-coated tablets.

Clarithromycin Teva 500 mg is available in pack sizes of 8, 10, 14, 14 calendar pack, 16, 20, 21, 30, 42 and 100 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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

Denmark	Clarithromycin Teva
Ireland	Clarithromycin Teva 250 mg & 500 mg film-coated tablets

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Advice/medical education

Antibiotics are used to cure bacterial infections. They are ineffective against viral infections.

If your doctor has prescribed antibiotics, you need them precisely for your current illness.

Despite antibiotics, some bacteria may survive or grow. This phenomenon is called resistance: some antibiotic treatments become ineffective.

Misuse of antibiotics increases resistance. You may even help bacteria become resistant and therefore delay your cure or decrease antibiotic efficacy if you do not respect appropriate:

- dosage
- schedules
- duration of treatment

Consequently, to preserve the efficacy of this drug:

- 1 - Use antibiotics only when prescribed.
- 2 - Strictly follow the prescription.
- 3 - Do not re-use an antibiotic without medical prescription, even if you want to treat a similar illness.
- 4 - Never give your antibiotic to another person; maybe it is not adapted to her/his illness.

5 - After completion of treatment, return all unused medicines to your pharmacist to ensure they will be disposed of correctly.