

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 using 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 use Clarithromycin Teva
3. How to use 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 use Clarithromycin Teva

Do not take Clarithromycin Teva

- if you are allergic to clarithromycin, other macrolide antibiotic (e.g. erythromycin, azithromycin) or any of the other ingredients of this medicine (listed in section 6)
- if you are taking medicines called terfenadine or astemizole (for hay fever or allergies) or cisapride (for stomach disorders) or pimozone (for mental illness) tablets as combining these drugs can sometimes cause serious disturbances in heart rhythm. Consult your doctor for advice on alternative medicines.
- if you are taking a medicine containing lomitapide
- if you have abnormally low levels of potassium or magnesium in your blood (hypokalaemia or hypomagnesaemia)
- 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 are taking ergotamine-like drugs (usually used for migraine)
- if you are taking simvastatin or lovastatin (to reduce cholesterol)
- if you have severe liver disease with kidney disease
- if you are taking ticagrelor (a blood-thinning drug)
- if you are taking ranolazine (used to treat angina)
- if you are taking colchicine (used to treat gout)

Warnings and precautions

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

- have liver problems
- have kidney problems
- have heart problems, in particular heart rhythm problems (e.g. long QT syndrome)
- if you have, or are prone to, fungal infections (e.g. thrush)
- if you are taking other medicines which are known to cause serious disturbances in heart rhythm (for the medicines terfenadine, astemizole, cisapride, and pimozide: see 'Do not take Clarithromycin Teva').

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 (to treat migraines)
- terfenadine or astemizole (used to treat hay fever and other allergies)
- pimozide (used to treat mental disorders)
- cisapride (used to treat stomach problems)
- simvastatin or lovastatin (used to lower cholesterol)
- colchicine (used to treat gout)
- ticagrelor (a blood-thinning drug)
- ranolazine (used to treat angina)

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

- warfarin or any other anticoagulant e.g. dabigatran, rivaroxaban, apixaban (used to thin your blood)
- medicines used to treat an abnormal heart beat, e.g. disopyramide or quinidine
- medicines used to treat heart failure, e.g. digoxin
- medicines used to treat epilepsy, e.g. phenytoin or carbamazepine
- theophylline, used to treat asthma
- benzodiazepines used as medicines that make you sleepy, e.g. midazolam, triazolam or alprazolam
- phenobarbital, used as a sedative and anti-convulsant
- rifabutin or rifampicin, rifapentine or aminoglycosides (e.g. gentamicin) used to treat some infections
- ciclosporin, tacrolimus or sirolimus, used following organ transplant
- medicines used to lower cholesterol, e.g. atorvastatin or rosuvastatin
- efavirenz, nevirapine, atazanvir, saquinavir, ritonavir, zidovudine or etravirine, used to treat HIV infected patients
- St John's Wort, 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.
- tolteridone, used to treat incontinence
- omeprazole, for the treatment of gastric ulcers
- medicines used to treat diabetes, e.g. insulin, glibenclamide, repaglinide nateglinide
- valproate, used to treat bipolar disorder
- eletriptan, aprepitant, halofantrine, ziprasidone, vinblastine, cilostazol, methylprednisolone
- verapamil, amlodipine or diltiazem, used to treat heart problems.

Clarithromycin Teva with food and drink

- You can take Clarithromycin Teva either with or without food, whichever you prefer

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. Ask your doctor or pharmacist for advice before taking any medicine. Small amounts of clarithromycin can pass into breast milk.

Driving and using machines

- Your tablets may make you feel sleepy, dizzy or confused. DO NOT drive or operate machinery if you are affected.

Clarithromycin Teva contains azo colours 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 use Clarithromycin Teva

Always use 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.

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 Teva 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 Teva 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 suffer from any of the following at any time during your treatment STOP TAKING your tablets and contact your doctor immediately:

- severe or prolonged diarrhoea, which may have blood or mucus in it. Diarrhoea may occur over two months after treatment with Clarithromycin Teva, in which case you should still contact your doctor.
- a rash, difficulty breathing, fainting or swelling of the face and throat. This is a sign that you may have developed an allergic reaction.
- 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 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).
- torsade de pointes, a life threatening irregular heart beat.

These are very serious but rare side effects. You may need urgent medical attention or hospitalisation.

Contact a doctor immediately if you experience a serious skin reaction: a red, scaly rash with bumps under the skin and blisters (exanthematous pustulosis). The frequency of this side effect is not known (cannot be estimated from the available data).

The following side effects have been reported at the approximate frequencies shown:

Common (may affect up to 1 in 10 people)

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

Uncommon (may affect up to 1 in 100 people)

- oral or vaginal 'thrush' (a fungal infection), vaginal bacterial infection
- reduction in the level of certain blood cells (which can make infections more likely or increase the risk of bruising or bleeding)
- loss of appetite, heartburn, bloating, constipation, wind
- anxiety, nervousness, drowsiness, tiredness, weakness, dizziness, tremor or shaking, or a general feeling of being unwell
- ringing in the ears or hearing loss
- vertigo
- inflammation of the mouth or tongue
- dry mouth
- joint pain
- chest pain or changes in heart rhythm such as palpitations
- a change in the levels of products made by the liver, inflammation of the liver, an inability of the liver to function properly or liver failure (you may notice yellowing of the skin, dark urine, pale stools or itchiness of the skin)
- abnormal blood test results

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

- swelling, redness or itchiness of the skin.

- angioedema (swelling of the face, lips and tongue)
- acne
- inflammation of the pancreas
- confusion, loss of bearings, hallucinations (seeing things), change in sense of reality or panicking, depression, abnormal dreams or nightmares, mania
- convulsion (fits)
- pins-and-needles (paraesthesia)
- bleeding
- discolouration of the tongue or teeth
- loss of taste or smell or inability to smell properly
- hearing loss
- muscle pain or loss of muscle tissue. If you suffer from myasthenia gravis (a condition in which the muscles become weak and tire easily) Clarithromycin Teva 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

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 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 to protect the environment.

6. Contents of the pack and other information

What Clarithromycin Teva Film-coated Tablets contains

- The active substance is clarithromycin. Each tablet contains either 250 mg or 500 mg of 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

- Each tablet contains either 250 mg or 500 mg of clarithromycin.
- The 250 mg tablet is a yellow, oval shaped film-coated tablet marked with “93” on one side and “7157” on the other.
- The 500 mg tablet is a light yellow, oval shaped film-coated tablet marked with “93” on one side and “7158” on the other.
- The 250 mg product is available in pack sizes of 8, 10, 12, 14, 14 calendar pack, 16, 20, 30, 100 and 120 tablets.
- The 500 mg product is available in pack sizes of 8, 10, 14, 14 calendar pack, 16, 20, 21, 30, 42 and 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer**Marketing Authorisation Holder:**

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2031GA Haarlem
The Netherlands

Manufacturer:

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

Denmark	Clarithromycin Teva
Finland	Clarithromycin ratiopharm 250 mg & 500 mg tabletti, Kalvopäällysteinen
Greece	Clarithromycin Teva 250 mg & 500 mg Επικαλυμμένα με λεπτό υμένιο δισκία
Ireland	Clarithromycin Teva 250 mg & 500 mg Film-coated Tablets
Portugal	Claritromicina Refta
Spain	Claritromicina Tevagen 250 mg & 500 mg comprimidos recubiertos con película EFG
United Kingdom	Clarithromycin 250 mg & 500 mg Film-coated Tablets

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