

Package leaflet: Information for the user

Clonocid 250mg Film-coated Tablets Clonocid 500mg 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 Clonocid film-coated tablets is and what it is used for
2. What you need to know before you take Clonocid film-coated tablets
3. How to take Clonocid film-coated tablets
4. Possible side effects
5. How to store Clonocid film-coated tablets
6. Contents of the pack and other information

1. What Clonocid film-coated tablets is and what it is used for

Clonocid film-coated tablets contain the active ingredient clarithromycin, which is an antibiotic (inhibits the growth of bacteria). Clonocid film-coated tablets are used when penicillin (another antibiotic) cannot be used. Clonocid film-coated tablets are used in adults and children 12 years and older for the following bacterial infections:

- Certain infections of the breathing tract:
 - acute sinusitis (inflammation of the sinuses) caused by bacteria
 - pharyngitis (sore throat), and tonsillitis (infection of the tonsils) in cases where more appropriate antibiotic treatment is not possible or susceptibility of the bacteria *Streptococcus pyogenes*, which caused the infection, has been shown
 - acute worsening of bronchitis (long-term inflammation of the bronchi [airways]), caused by bacteria,
 - and pneumonia caused by atypical bacteria.
- Some skin and soft tissue infections such as
 - erythrasma (a skin disease that can result in pink patches)
 - acne vulgaris (a skin condition, characterised by reddish papules or pustules)
 - erysipelas (local reddening of the skin)
 - if more appropriate antibiotic treatment is not possible.
- In combination with other antibiotics and an ulcer treatment for treating *Helicobacter pylori* (an infection that is linked to ulcers).

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

DO NOT take Clonocid film-coated tablets if you:

- are allergic to clarithromycin, other macrolides (similar antibiotics such as erythromycin or azithromycin), or any of the other ingredients of this medicine (listed in section 6). An allergic reaction may include rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.
- are **taking:**
 - **ergotamine-like medicines** (usually used for migraine)

- **terfenadine** or **astemizole** (taken for hay fever or allergies) or **cisapride** (used for stomach disorders and heartburn) or **pimozide** (for mental illness) tablets as combining these drugs can sometimes cause serious disturbances in heart rhythm.
- Consult your doctor for advice on alternative medicines.
- **statins** such as **simvastatin** or **lovastatin** (treatments to lower cholesterol)
- **ticagrelor** (a medicine which prevents your blood from clotting)
- **ranolazine** (a medicine used to treat angina pectoris)
- **colchicines** (usually taken for gout)
- other medicines which are known to cause serious disturbances in heart rhythm
- 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
- have abnormally low levels of potassium in your blood (hypokalaemia)
- have severe liver as well as kidney problems.

Warnings and precautions

Talk to your doctor or pharmacist before taking Clonocid film-coated tablets. Especially if you:

- develop severe diarrhoea during or after treatment with Clonocid film-coated tablets - stop taking the tablets and tell your doctor. Do not take medicines that prevent peristalsis (bowel movement) such as anti-diarrhoea treatments before the reason for your diarrhoea has been clarified.
- develop another infection - stop taking the tablets and tell your doctor
- have a kidney and/or liver disorder
- are allergic to other antibiotics
- have a heart disorder
- have abnormally low levels of magnesium in your blood (hypomagnesaemia)

If any of the above applies to you, speak to your doctor.

Other medicines and Clonocid film-coated tablets

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

You should not take Clonocid film-coated tablets if you are taking any of the medicines listed in the section “**DO NOT take Clonocid film-coated tablets if you**” above.

Tell your doctor if you are taking any of the following medicines as your dose may need to be changed or you may need to have regular tests performed:

- digoxin, quinidine or disopyramide (for heart problems)
- triazolam, alprazolam, midazolam (sedatives)
- cilostazol (for poor circulation)
- St. John’s Wort (herbal product used for depression)
- ciclosporin, tacrolimus or sirolimus (help prevent rejection after a transplant)
- theophylline (for asthma)
- methylprednisolone (a corticosteroid)
- vinblastine (for treatment of cancer)
- rifabutin, rifampicin, rifapentine, fluconazole, itraconazole (treatments for infectious diseases)
- ritonavir, efavirenz, nevirapine, atazanavir, saquinavir, etravirine or zidovudine (anti-viral drugs used in the treatment of HIV)
- warfarin (medicine for blood thinning)
- atorvastatin, or rosuvastatin (HMG-CoA reductase inhibitors, commonly known as statins, and used to lower levels of cholesterol (a type of fat) in the blood)
- omeprazole (used for the treatment of indigestion and gastric ulcers) unless your doctor has prescribed it for you to treat *Helicobacter pylori* infection associated with duodenal ulcer
- aprepitant (for stomach disorders)
- phenytoin, carbamazepine, valproate or phenobarbital (for epilepsy)

- insulin or other diabetes medicines (such as tolbutamide, gliclazide, glibenclamide, nateglinide, repaglinide)
- colchicine (usually taken for gout)
- aminoglycoside antibiotics such as streptomycin or gentamicin
- verapamil, amlodipine, diltiazem (for high blood pressure and irregular heart beat)
- tolterodine (for overactive bladder)
- sildenafil, vardenafil and tadalafil (for impotence in adult males or for use in pulmonary arterial hypertension (high blood pressure in the blood vessels of the lung))
- quetiapine (an antipsychotic)

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

Clonocid film-coated tablets with food

Clonocid 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 for advice before taking this medicine.

You should tell your doctor if you are pregnant or breast-feeding and your doctor will decide if it is o.k. for you to take Clonocid film-coated tablets.

Driving and using machines

Clonocid 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 Clonocid 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.

Adults, the elderly and children over 12 years:

The recommended dose is 250 mg twice daily. This may be increased to 500 mg twice daily for severe infections.

The recommended dose for *H. pylori* as part of a treatment for duodenal ulcers is 500 mg twice daily. Patients with a severe kidney disorder may need a reduced dose (250 mg once daily or 250 mg twice daily for more severe infections) and their treatment should not be longer than 14 days.

Method of administration

Clonocid film-coated tablets may be taken with or without food.
Clonocid 500 mg film-coated tablets can be divided into equal doses.

Use in children

Clonocid film-coated tablets are not suitable for children less than 12 years of age or who weigh less than 30 kg.

Duration of treatment

The usual length of treatment is 6 to 14 days. Treatment is continued for at least 2 days after the symptoms of the infection have gone.

If you take more Clonocid film-coated tablets than you should

Contact your doctor, pharmacist or nearest hospital immediately.

If you forget to take Clonocid 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 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.

All medicines can cause allergic reactions, although serious allergic reactions are very rare. **Tell your doctor straight away if you get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body).**

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:

Common (may affect up to 1 in 10 people)

- difficulty in sleeping or sleeplessness (insomnia)
- headache
- nausea (feeling sick)
- vomiting
- diarrhoea (see also 'Warnings and precautions')
- stomach pain
- indigestion
- pain in the stomach region
- rash
- increased sweating
- altered taste (for example metallic or bitter taste)
- altered liver function tests

Uncommon (may affect up to 1 in 100 people)

- allergic reactions such as itchy skin, skin eruption or shock (drop of blood pressure, restlessness, weak rapid pulse, clammy skin, reduced consciousness) - **if this happens tell your doctor straight away.**
- dizziness
- drowsiness
- feeling of dizziness or spinning (vertigo)
- tinnitus (ringing in the ears)
- hearing impaired
- dry mouth
- belching
- bloating (feeling uncomfortably full and the presence of rumbling sounds in the stomach)
- flatulence
- inflammation of the stomach lining
- decreased appetite or loss of appetite
- anxiety
- difficulty to pass stools (constipation)
- general discomfort
- feeling of weakness
- chest pain
- tiredness
- shivering (chills)
- shaking
- abnormal ECG heart tracing (QT prolongation)
- feeling your heartbeat (palpitation)
- liver disturbances (raised liver enzymes while having a blood test)
- hepatitis (inflammation of the liver)
- cholestasis (bile disorder)

- diverse infections including infection of the vagina and infection by fungi in the mouth
- inflammation in the mouth or of the tongue
- low counts of white blood cells
- abnormal increase in eosinophils (a certain type of white blood cells)
- increase in the levels of a certain enzyme within the body (seen in a blood test)

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

- serious allergic reaction which causes difficulty in breathing or dizziness - **if this happens tell your doctor straight away**
- allergic reactions including rash and exanthema (DRESS syndrome)
- angioedema (serious allergic reaction which causes swelling, especially of the face, mouth, tongue or throat) - **if this happens tell your doctor straight away**
- pseudo-membranous colitis (an illness with diarrhoea, fever, and abdominal pain – in severe cases, life-threatening complications can develop)
- liver failure (particularly in patients with liver disease or patients taking other medicine that may be harmful for the liver)
- faster heartbeat
- changes in heartbeat rhythm
- life-threatening irregular heartbeat
- inflammation of the pancreas (combined with severe pain in the upper abdominal region radiating to the back, along with nausea and vomiting)
- change or loss in the sense of taste or smell
- discoloration of teeth and tongue
- pain or weakness in muscles
- abnormal muscle breakdown which can lead to kidney problems
- inflammation of kidneys (combined with blood in the urine, fever, and pain in the sides)
- severely reduced kidney function (renal failure)
- severe reduction in number of white blood cells which makes infections more likely
- abnormally low counts of blood platelets (which may cause bruising of the skin or increased tendency to bleed)
- bleeding (haemorrhage)
- long blood clotting time
- seeing things (hallucinations)
- abnormal thoughts (psychotic disorder)
- disorientation (not knowing where you are)
- depersonalization (out of body feeling)
- bad dreams
- feeling elated or over-excited (mania)
- confusion
- convulsions (fits)
- Stevens-Johnson syndrome or toxic epidermal necrolysis (severe peeling and blistering of the skin)
- hearing loss
- depression
- jaundice (yellowing of the skin or eyes)
- skin eruptions (acne)
- very red skin (erysipelas)
- dark urine
- sensation of “pins and needles” in the skin (paraesthesia)

There have also been reports that clarithromycin may worsen the symptoms of myasthenia gravis (a condition in which the muscles become weak and tire easily) in patients who already suffer from this condition.

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; 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 Clonocid 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. The expiry date refers to the last day of that month.

Do not store above 30°C.

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 Clonocid film-coated tablets contain:

The active substance is clarithromycin.

Clonocid film-coated tablets contain 250 or 500 mg of the active substance clarithromycin.

The tablets also contain the following ingredients: Croscarmellose sodium, microcrystalline cellulose, colloidal anhydrous silica, povidone (K 30), stearic acid, magnesium stearate and talcum.

The coating contains: Hypromellose, propyleneglycol, hydroxypropylcellulose, talcum, titanium dioxide (E171), quinoline yellow (E104) and vanillin.

What Clonocid film-coated tablets looks like and contents of the pack

Clonocid 250 mg are light yellow coloured, oval shaped biconvex film coated tablets, embossed with C1 on one side.

Clonocid 500 mg are light yellow coloured, oval shaped biconvex film coated tablets with C and 2 embossed on either side of breakline on one side and notched on either sides along with the breakline.

250 mg

Blister packs of: 1, 2, 7, 10, 12, 14, 15, 16, 20, 21, 28, 30, 32, 42, 50, 56, 60, 90, 100, 250, or 500 tablets.

500 mg

Blister packs of: 1, 7, 10, 12, 14, 20, 21, 28, 30, 32, 42, 50, 60, 90, 100, 250, or 500 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder:

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary

Manufacturers:

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary

Ranbaxy Ireland Ltd, Spafield, Cork Road, Cashel, Co. Tipperary

Centrafarm Services B.V., Nieuwe Donk 9, 4879 AC –Etten Leur, The Netherlands

STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel, Germany

STADA Arzneimittel GmbH, Muthgasse 36/2, 1190 Wien, Austria

STADApHarm GmbH, Stadastrasse 2-18, 61118 Bad Vilbel, Germany

Sanico N.V. Veedijk 59, Industriezone IV, Turnhout, Belgium

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

AT:	Clarithromycin Stada 250 mg Filmtabletten Clarithromycin Stada 500 mg Filmtabletten
BE/LU:	Clarithromycine EG 250 mg filmomhulde tabletten Clarithromycine EG 500 mg filmomhulde tabletten
DK:	Clarithromycin STADA
IE:	Clonocid 250 mg Tablets Clonocid 500 mg Tablets
IT:	Claritromicina EG 250 mg, compresse rivestite con film Claritromicina EG 500 mg, compresse rivestite con film

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