

## 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 is and what it is used for
2. What you need to know before you take Clonocid
3. How to take Clonocid
4. Possible side effects
5. How to store Clonocid
6. Contents of the pack and other information

#### **1. What Clonocid is and what it is used for**

Clonocid contains the active ingredient clarithromycin, which is an antibiotic (inhibits the growth of bacteria). Clonocid is used when penicillin (another antibiotic) cannot be used. Clonocid is 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**

##### **DO NOT take Clonocid 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)
- a medicine containing **lomitapide** (treatment to lower cholesterol)
- **ticagrelor, ivabradine or ranolazine** (for angina or to reduce the chance of heart attack or stroke)
- **colchicine** (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 or magnesium in your blood (hypokalaemia or hypomagnesaemia)
- have severe liver as well as kidney problems.

### Warnings and precautions

Talk to your doctor or pharmacist before taking Clonocid. Especially if you:

- develop severe diarrhoea during or after treatment with Clonocid - 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

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

### Other medicines and Clonocid

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

You should not take Clonocid if you are taking any of the medicines listed in the section “**DO NOT take Clonocid 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, or any other anticoagulant e.g. dabigatran, rivaroxaban, apixaban, edoxaban (used to thin your blood)
- 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)
- 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)

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

### **Clonocid with food**

Clonocid 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.

### **Driving and using machines**

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

### **Clonocid contains propylene glycol (E1520) and sodium**

This medicine contains 12.315 mg propylene glycol in each tablet.

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

## **3. How to take Clonocid**

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 may be taken with or without food.

Clonocid 500 mg film-coated tablets can be divided into equal doses.

### **Use in children**

Clonocid 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 than you should**

Contact your doctor, pharmacist or nearest hospital immediately.

### **If you forget to take Clonocid**

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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

Ireland:

HPRA Pharmacovigilance

Website: [www.hpra.ie](http://www.hpra.ie)

Malta:

ADR Reporting

Website: [www.medicinesauthority.gov.mt/adrportal](http://www.medicinesauthority.gov.mt/adrportal)

By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store Clonocid**

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 contains:**

The active substance is clarithromycin.

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

The other ingredients are:

#### Tablet core:

Croscarmellose sodium, microcrystalline cellulose, colloidal anhydrous silica, povidone (K 30), stearic acid, magnesium stearate and talcum.

#### Film-coating:

Hypromellose, propylene glycol (E1520), hydroxypropylcellulose, talcum, titanium dioxide (E171), quinoline yellow (E104) and vanillin.

#### **What Clonocid 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

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

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

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 Filmdabletten Clarithromycin Stada 500 mg Filmdabletten
BE/LU:	Clarithromycine EG 250 mg filmomhulde tableten Clarithromycine EG 500 mg filmomhulde tableten
DK:	Clarithromycin STADA
IE:	Clonocid 250 mg Tablets Clonocid 500 mg Tablets
MT:	Clonocid 250 mg film-coated tablets Clonocid 500 mg film-coated tablets
IT:	Claritromicina EG 250 mg, compresse rivestite con film Claritromicina EG 500 mg, compresse rivestite con film

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