

## Package leaflet: Information for the user

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

#### 1. What Clarithromycin tablets is and what it is used for

Clarithromycin tablet contains the active ingredient clarithromycin which belongs to a group of medicines called macrolide antibiotics.

Antibiotics stop the growth of certain bacteria which cause infections.

Clarithromycin tablets is used to treat bacterial infections, which previously have to be adequately diagnosed by your treating physician such as:

- Chest infections such as bronchitis and community acquired pneumonia
- Throat and sinus infections
- Skin and tissue infections (e.g. impetigo, erysipelas, erythrasma)
- In combination with appropriate ulcer healing *Helicobacter pylori* infection associated with duodenal ulcer (restricted to adults only).

Clarithromycin tablets are indicated in adults and adolescents 12 years and older.

#### 2. What you need to know before you take Clarithromycin tablets

##### Do not take Clarithromycin 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
  - ergotamine-like drugs (medicines for the treatment of acute migraine attacks)
  - astemizole or terfenadine (medicines for the treatment of hay fever or allergies)
  - cisapride or domperidone (medicine used for the treatment of digestive problems)
  - pimozide (medicine for the treatment of psychoses)
  - colchicine (medicine for the treatment of gout)
  - lovastatin, simvastatin or atorvastatin (medicines to reduce cholesterol levels (a certain type of fat) in the blood)
  - other medicines which are known to cause serious disturbances in heart rhythm
  - medicines called ticagrelor or ranolazine (for angina or to reduce the chance of heart attack or stroke)

- a medicine containing lomitapide
- you have abnormally low levels of potassium or magnesium in your blood (hypokalaemia or hypomagnesaemia)
- you have severe liver disease in combination with kidney disease
- oral midazolam (for anxiety or to help sleep).
- you have an irregular heart rhythm
- you or someone in your family has a history of heart rhythm disorders (ventricular cardiac arrhythmia, including torsades de pointes) or abnormality of electrocardiogram (ECG, electrical recording of the heart) called “long QT syndrome”.

### **Warnings and precautions**

Talk to your doctor or, pharmacist before taking Clarithromycin tablets if:

- you are allergic to the antibiotics lincomycin or clindamycin
- you have any liver or kidney problems
- you have heart problems, in particular heart rhythm problems (e.g. long QT syndrome)
- you have or are prone to fungal infections (e.g. thrush)
- you have diabetes
- you are pregnant or breast-feeding
- if you need to have intravenous or oromucosal (absorbed in the mouth) midazolam

If any of these apply to you, consult your doctor before taking clarithromycin tablets.

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

### **Children under 12 years of age**

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

### **Other medicines and Clarithromycin tablets**

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

### **Do not take Clarithromycin tablets if you are taking:**

- ergotamine, dihydroergotamine (medicines for the treatment of migraine)
- terfenadine or astemizole (medicines for the treatment of hay fever or allergies)
- cisapride (medicine for the treatment of digestive problems)
- pimozone (medicines for the treatment of psychiatric disorders)
- colchicine (medicine for the treatment of gout)
- simvastatin or lovastatin (medicines used to lower cholesterol)
- ticagrelor, ivabradine or ranolazine (medicines for the treatment of heart problem)
- You are taking a medicine containing lomitapide

Care is needed if you are taking

- digoxin, disopyramide or quinidine (medicines for the treatment of various heart conditions)
- cilostazol (medicine for the treatment of poor blood circulation)
- methylprednisolone (a corticosteroid)
- oral anticoagulants (e.g., warfarin, dabigatran, rivaroxaban, apixaban, edoxaban; used to thin the blood)
- nateglinide, pioglitazone, repaglinide, rosiglitazone or insulin (medicines to lower blood glucose levels)
- sildenafil, vardenafil and tadalafil (medicines for the treatment of impotence in adult males or to treat high blood pressure in the blood vessels of the lungs)
- vinblastine (medicine for the treatment of cancer)
- valproate, carbamazepine, phenobarbital or phenytoin (medicines for the treatment of epilepsy)

- theophylline (medicine for the treatment of breathing problems)
- omeprazole (medicine 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)
- ciclosporin, sirolimus or tacrolimus (used to prevent organ rejection after transplant)
- etravirine, efavirenz, nevirapine, atazanavir, saquinavir, zidovudine or ritonavir (medicines used for the treatment of human immunodeficiency virus [HIV]infection)
- rifampicin, rifapentine, fluconazole, itraconazole or rifabutin (medicines used for the treatment of certain infections)
- tolterodine (medicine for the treatment of an overactive bladder)
- verapamil (medicine for the treatment of high blood pressure)
- St John's wort (a herbal medicinal product used to treat depression)
- benzodiazepine drugs such as midazolam, triazolam and alprazolam used as sedatives
- 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)

Clarithromycin does not interact with oral contraceptives.

#### **Clarithromycin tablets with food and drink**

Clarithromycin 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, do not take Clarithromycin tablets without consulting your doctor first.

#### **Driving and using machines**

Clarithromycin tablets may make you feel sleepy, dizzy or confused, vertigo and disorientation. Do not drive or operate machinery if you are affected.

#### **Clarithromycin tablets contain sodium**

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

### **3. How to take Clarithromycin tablets**

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

The recommended dosage is:

#### **Adults and adolescents (aged 12 years and older)**

- **For chest infections, throat or sinus infections and skin and soft tissue infections:**  
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 tablets 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.

#### **Use in children and adolescents**

Clarithromycin tablets is not recommended for use in children under 12 years of age. For these patients other pharmaceutical forms e.g., suspensions are available.

### **Hepatic or renal impairment**

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

### **Method of administration**

Clarithromycin tablets should be swallowed preferably with a glass of water.

### **If you take more Clarithromycin tablets than you should**

If you accidentally take more tablets in one day than your doctor has told you to, or if a child accidentally swallows some tablets, contact your doctor or nearest hospital emergency department 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 tablets**

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 more tablets in one day than your doctor has told you to **Do not** take a double dose to make up for a forgotten dose.

### **If you stop taking Clarithromycin tablets**

Do not stop taking your medicine because you are feeling better. It is important to take the tablets for as long as the doctor has told you to, otherwise the problem might 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, 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).
- Fast or irregular heart beat
- Severe pain in the abdomen and back, caused by inflammation of the pancreas.

### **Common side effects (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 side effects (may affect up to 1 in 100 people):**

- oral or vaginal ‘thrush’ (a fungal 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, 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 the available data):**

- swelling, redness or itchiness of the skin. Sometimes brown scales may appear small palpable bleedings in the skin, often with joint and abdominal pain (Henoch-Schönleins purpura), contact a doctor immediately if you experience a serious skin reaction: a red, scaly rash with bumps
- swelling of the skin around the face and the throat. This may cause difficulty in breathing (angioedema)
- under the skin and blisters (exanthematous pustulosis).
- acne
- inflammation of the pancreas
- confusion, loss of bearings, hallucinations (seeing things), change in sense of reality or panicking, depression, abnormal dreams or nightmares, manic episodes
- convulsion (fits)
- bleeding
- discolouration of the tongue or teeth
- loss of taste or smell or inability to smell properly
- deafness
- 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 may worsen these symptoms
- low blood sugar levels  
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 or 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](http://www.hpra.ie)

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

**5. How to store Clarithromycin 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 on the blister after EXP. The expiry date refers to the last day of that month.

This medicinal product 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 to protect the environment.

## **6. Contents of the pack and other information**

### **What Clarithromycin tablets contains**

- Each Clarithromycin tablet contains 250 mg or 500 mg of the active ingredient clarithromycin.
- The other ingredient(s) are:  
Tablet core: Cellulose, microcrystalline (E460), Croscarmellose sodium, Povidone K30, Talc (E553b), Colloidal anhydrous silica, Magnesium stearate (E470b), Stearic acid 50.  
Film-coating: Opadry Yellow contains Hypromellose 2910 (5mPa.s) (E464), Propylene glycol (E1520), Titanium dioxide (E171), Vanillin, Hydroxypropylcellulose (E463), Talc (E553b), Quinoline yellow (E104)

### **What Clarithromycin tablets looks like and contents of the pack**

Clarithromycin 250mg tablets are Light yellow coloured, oval shaped, biconvex, film coated tablets, debossed with 'C1' on one side. 250mg tablet length is approximately 14.90 mm and width is approximately 7.10 mm.

Clarithromycin 500mg tablets are Light yellow coloured, oval shaped, biconvex, film coated tablets, with 'C' and '2' debossed on either side of break line on one side. The tablet can be divided into equal doses. 500mg tablet length is approximately 18.60 mm and width is approximately 8.85 mm.

Clarithromycin 250mg tablets are available in blister strips of 10, 12, 14, 16, 20, 21, 30, 250 or 500 tablets and Clarithromycin 500mg tablets are available in blister strips of 7, 10, 14, 16, 20, 21, 28, 30, 250 or 500 tablets.

Not all pack sizes may be marketed.

## **Marketing Authorisation Holder and Manufacturer**

### **Marketing Authorisation Holder:**

Accord Healthcare Ireland Ltd,  
Euro House,  
Euro Business Park,  
Little Island,  
Cork T45 K857,  
Ireland

### **Manufacturer:**

Accord Healthcare B.V.,  
Winthontlaan 200,  
3526 KV Utrecht,  
The Netherlands

LABORATORI FUNDACIÓ DAU  
C/ C, 12-14 Pol. Ind. Zona Franca,  
Barcelona, 08040 Barcelona,  
Spain

Accord Healthcare Polska Sp.z o.o.,  
ul. Lutomska 50,95-200 Pabianice, Poland

**This medicinal product is authorised in the Member States of the European Economic Area under the following names:**

<b>Name of the member state</b>	<b>Name of the medicine</b>
The Netherlands	Clarithromycin Accord 250/500 mg filmomhulde tabletten
Austria	Clarithromycin Accord 250/500 mg Filmtabletten
Germany	Clarithromycin Accord 250/500 mg Filmtabletten
Denmark	Clarithromycin Accord
Spain	Claritromicina Accord 500 mg comprimidos recubiertos con película EFG
France	Clarithromycin Accord 250/500 mg comprimé pelliculé
Ireland	Clarithromycin 250/500 mg film-coated tablets
Italy	Claritromicina Accord 250/500 mg compresse rivestite con film
Norway	Clarithromycin Accord 250/500 mg filmdrasjerte tabletter

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