

Package leaflet: information for the user

Clarithromycin Accord 250 mg film-coated tablets
Clarithromycin Accord 500 mg film-coated tablets
clarithromycin

Read the entire 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.
- Do you have any questions? Contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed for you only. It may harm them, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor or pharmacist.

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1. What is Clarithromycin Accord and what is it used for?

Clarithromycin Accord tablets contain the active substance clarithromycin, which belongs to a group of medicines called macrolide antibiotics.

Antibiotics stop the growth of certain bacteria that cause infections.

This medicine is used to treat bacterial infections, which must first be diagnosed by your treating doctor, such as:

- Respiratory tract infections, such as inflammation of the airways with coughing and the production of mucus (bronchitis) and pneumonia acquired outside the hospital
- Infections of the throat and nasal sinuses
- Infections of the skin and tissues located under the skin, around the organs and bones, or in the spaces between them (soft tissues) (for example, a skin infection that mainly occurs in children (impetigo), a skin and subcutaneous tissue infection (erysipelas) and a skin infection that mainly occurs in body folds such as the groin and armpits (erythrasma))
- In combination with a medicine that heals duodenal ulcers caused by an infection with the bacterium *Helicobacter pylori* (adults only)

This medicine is used in adults and adolescents aged 12 years and older.

2. When should you not use this medicine or be extra careful with it?

When should you not use this medicine?

- You are allergic to any of the ingredients in this medicine. These ingredients can be found in section 6. Or you are allergic to other macrolide antibiotics, such as erythromycin or azithromycin.
- You are using:
 - ergotamine-like medicines (medicines for the treatment of sudden (acute) migraine attacks) astemizole or terfenadine (medicines for the treatment of hay fever or allergies) cisapride or domperidone (medicine for the treatment of digestive problems)
 - pimozide (medicine for the treatment of a severe mental illness where control over one's own thinking, behavior, and actions is disturbed; contact with reality is also disturbed (psychosis))
 - colchicine (medicine for the treatment of gout)
 - lovastatin, simvastatin, or atorvastatin (medicines that lower the amount of cholesterol (a certain type of fat) in the blood)
 - other medicines known to cause serious disturbances in heart rhythm
 - medicines called ticagrelor or ranolazine (for the treatment of angina or to reduce the risk of a heart attack or stroke) You are using a medicine that contains lomitapide
- You have an abnormally low potassium or magnesium level in your blood (hypokalemia or hypomagnesemia)
- You have a severe liver disorder in combination with a kidney disorder
- You take midazolam orally (for the treatment of anxiety or to help with sleeping)
- You have an irregular heartbeat
- You or someone in your family has ever had heart rhythm disorders (ventricular arrhythmia, including torsades de pointes) or an abnormality in the electrocardiogram (ECG or heart film, an electrical 'recording' of the heart) called 'long QT syndrome'.

When should you be extra careful with this medicine?

- Contact your doctor or pharmacist before using this medicine:
- if you are allergic to lincomycin or clindamycin, medicines against certain bacterial infections (antibiotics)
- if you have liver or kidney problems
- if you have heart problems, especially problems with your heart rhythm (e.g., a prolonged QT interval)
- if you are prone to fungal infections (e.g., thrush)
- if you have diabetes
- if you are pregnant or breastfeeding

If one or more of these things apply to you, talk to your doctor before taking clarithromycin tablets.

If you experience severe or prolonged diarrhea during or after using clarithromycin tablets, tell your doctor immediately. This may be a sign of more serious conditions such as pseudomembranous colitis or Clostridioides difficile-associated diarrhea.

- if you need to receive midazolam intravenously or oromucosally (via the oral mucosa)

Children under 12 years

This medicine is not suitable for use by children under 12 years.

Are you using any other medicines?

Are you using any other medicines besides Clarithromycin Accord, have you done so recently, or are you planning to do so soon? Tell your doctor or pharmacist.

Do not use this medicine if you are using any of the following medicines:

- ergotamine, dihydro-ergotamine (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)
- pimoziide (medicine for the treatment of mental disorders)
- colchicine (medicine for the treatment of gout)
- simvastatin or lovastatin (medicines to lower the amount of cholesterol in the blood)
- ticagrelor or ranolazine (medicines for the treatment of heart problems)
- You are using a medicine that contains lomitapide

You must be extra careful if you take the following:

- digoxin, disopyramide or quinidine (medicines for the treatment of various heart conditions)
- cilostazol (medicine for the treatment of poor circulation)
- methylprednisolone (an adrenal cortex hormone (corticosteroid))
- medicines that counteract blood clotting (oral anticoagulants, for example warfarin, dabigatran, rivaroxaban, apixaban)
- nateglinide, pioglitazone, repaglinide, rosiglitazone or insulin (medicines that lower blood sugar levels)
- sildenafil, vardenafil and tadalafil (medicines for the treatment of impotence in adult men or for the treatment of 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 respiratory problems)
- omeprazole (medicine for the treatment of digestive disorders and stomach ulcers), unless your doctor has prescribed them for the treatment of duodenal ulcers due to infections with *Helicobacter pylori*)
- ciclosporin, sirolimus or tacrolimus (used to prevent rejection of transplanted organs)
- etravirine, efavirenz, nevirapine, atazanavir, saquinavir, zidovudine or ritonavir (medicines for the treatment of HIV infections (human immunodeficiency virus))
- rifampicin, rifapentine, fluconazole, itraconazole or rifabutin (medicines 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 (an herbal medicine for the treatment of depression)
- medicines called benzodiazepines such as midazolam, triazolam, and alprazolam (medicines with calming, sleep-inducing and/or muscle-relaxing effects)

Clarithromycin Accord does not interact with medicines to prevent pregnancy (contraceptives) that are taken orally.

What should you pay attention to with food and drink?

This medicine can be taken with or without food.

Pregnancy and breastfeeding

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor before using this medicine.

Driving and using machines

This medicine may make you feel sleepy, dizzy, confused, lightheaded, or disoriented. If you experience these effects, do not drive or operate machinery.

Clarithromycin Accord tablets contain sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, which means it is essentially 'sodium-free'.

3. How do you use this medicine?

Always take this medicine exactly as your doctor or pharmacist has told you. If you are unsure about the correct use, contact your doctor or pharmacist.

The recommended dosage is:

Adults and adolescents (12 years and older):

- For infections of the respiratory tract, throat, sinuses, skin, and tissues under the skin, around the organs and bones, or in the spaces between them (soft tissues): 250 mg twice daily. In severe infections, your doctor may increase the dose to 500 mg twice daily. The usual treatment duration is 6 to 14 days.
- For the treatment of an infection with *Helicobacter pylori*, associated with duodenal ulcers: This medicine should be taken at a dose of 500 mg twice daily in combination with other medicines to treat *Helicobacter pylori*. Your doctor will decide what the best combination therapy is for you. If you are unsure which medications to take and when, contact your doctor.

Use in children and adolescents up to 18 years

This medicine is not suitable for use by children under 12 years. For these patients, other forms of administration, such as suspensions, are available.

Reduced liver or kidney function

If you have liver or severe kidney problems, your doctor may need to lower the dose. This medicine should not be used for more than 14 days if you have these problems.

Method of administration

Clarithromycin Accord tablets should be swallowed whole with a glass of water.

Have you taken too much of this medicine?

If you accidentally take more tablets in one day than your doctor has prescribed, or if a child accidentally swallows tablets, you should contact your doctor or hospital immediately. Overdose is likely to cause vomiting and stomach discomfort.

Take this leaflet, the remaining tablets, and the packaging with you to the hospital or your doctor, so they know which tablets have been taken.

Have you forgotten to take this medicine?

If you have forgotten to take your tablet, do so as soon as you remember, unless it is almost time for the next dose. Do not take more tablets in one day than your doctor has told you.

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

If you stop using this medicine

Do not stop using this medicine because you feel better. It is important that you take your medicine according to your doctor's instructions, otherwise the symptoms may return and this medicine may work less well next time.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

Like any medicine, this medicine can also have side effects. Not everyone gets them.

If you experience any of the following symptoms during your treatment, STOP using the tablets and contact your doctor immediately:

- severe or persistent diarrhea, sometimes with blood or mucus in it. Diarrhea can occur up to two months after treatment with clarithromycin, and you should still contact your doctor.
- skin rash, difficulty breathing, fainting, or swelling of the face or throat. This is a sign that you may have developed an allergic reaction;
- yellowing of the skin (jaundice), skin irritation, pale stools, dark urine, abdominal pain, or decreased appetite. These symptoms may indicate impaired liver function;
- 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);
- rapid or irregular heartbeat
- severe pain in the abdomen and back, caused by inflammation of the pancreas.

Side effects that are common (occur in less than 1 in 10 users)

- headache
- difficulty sleeping
- altered taste
- stomach problems, such as nausea, vomiting, abdominal pain, digestive problems, diarrhea
- abnormal liver function (seen in blood results)
- skin rash
- increased sweating

Side effects that are uncommon (occur in less than 1 in 100 users)

- oral or vaginal thrush (a fungal infection)
- reduction in the number of certain blood cells (increasing the chance of infection or the risk of bruising or bleeding)
- decreased appetite, heartburn, bloating, constipation, flatulence
- anxiety, nervousness, drowsiness, fatigue, dizziness, involuntary trembling (tremor) or shaking, or a general feeling of being unwell
- ringing in the ears or hearing loss
- vertigo with balance disorder (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 amounts of products made by the liver, inflammation of the liver, inability of the liver to function properly or liver failure (you may notice yellowing of the skin, dark urine, pale stools, or an itchy skin)
- abnormal blood test results

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

- swelling, redness, or itching of the skin. Sometimes a brown scaly rash may appear. Additionally, small palpable bleedings in the skin, often accompanied by joint or abdominal pain, may occur (Henoch-Schönlein purpura). Contact a doctor immediately if you experience a severe skin reaction: a red, scaly rash with blisters filled with pus with a red surrounding skin (exanthematous pustulosis).
- swelling of the skin around the face and throat. This can lead to difficulty breathing (angioedema)
- acne
- pancreatitis
- confusion, feeling lost/disoriented, perceptions (seeing, hearing, smelling, feeling) of things that are not there (hallucinations), change in sense of reality or panic attacks, a depressed mood, abnormal dreams or nightmares, manic episodes
- seizure with muscle twitching (convulsion) bleeding
- discoloration 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 a condition where muscles weaken and tear quickly (myasthenia gravis), clarithromycin may worsen these symptoms
- low blood sugar level
- inflammation of the kidneys or inability of the kidneys to function properly (you may notice fatigue, swelling or bloating in the face, abdomen, thighs, or ankles, or problems urinating) or kidney failure

Reporting side effects

If you experience side effects, contact your doctor, pharmacist, or nurse. This also applies to possible side effects not listed in this leaflet. You can also report side effects via the Netherlands Pharmacovigilance Centre Lareb. Website: www.lareb.nl. By reporting side effects, you help us obtain more information about the safety of this medicine.

5. How should you store this medicine?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. It can be found on the box and the blister pack after EXP. It includes a month and a year. The last day of that month is the expiry date.

There are no special storage conditions for this medicine regarding temperature. Store in the original packaging to protect from moisture.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. Proper disposal of medicines ensures they are destroyed correctly and do not enter the environment.

6. Contents of the packaging and other information

What substances are in this medicine?

- The active substance in this medicine is clarithromycin. Each tablet contains 250 or 500 mg of clarithromycin.
- The other substances in this medicine are:
Tablet core: Microcrystalline cellulose (E460), croscarmellose sodium, povidone K30, talc (E553b), colloidal anhydrous silica, magnesium stearate (E470b), stearic acid 50
Film coating (: Opadry Yellow): hypromellose 2910 (5mPa.s) (E464), propylene glycol (E1520), titanium dioxide (E171), vanillin, hydroxypropyl cellulose (E463), talc (E553b), quinoline yellow aluminum lake (E104)

What does Clarithromycin Accord look like and what is in a package?

Clarithromycin Accord 250 mg film-coated tablets are light yellow, oval, biconvex, film-coated tablets with the imprint 'C1' on one side. The 250 mg film-coated tablet is approximately 14.90 mm long and approximately 7.10 mm wide.

Clarithromycin Accord 500 mg film-coated tablets are light yellow, oval, biconvex, film-coated tablets with the imprint 'C' and '2' on either side of the score line on one side. The tablet can be divided into equal doses. The 500 mg film-coated tablet is approximately 18.60 mm long and approximately 8.85 mm wide.

Clarithromycin Accord 250 mg film-coated tablets are available in blister packs of 10, 12, 14, 16, 20, 21, 30, 250 or 500 tablets and Clarithromycin Accord 500 mg film-coated tablets are available in blister packs of 7, 10, 14, 16, 20, 21, 28, 30, 250 or 500 tablets.

Not all pack sizes may be marketed.

Marketing authorization holder and manufacturer

Marketing authorization holder

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

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

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

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

Accord Healthcare Single Member S.A.
64th Km National Road Athens,
Lamia, 32009, Greece

Registered under:

Clarithromycin Accord 250 mg film-coated tablets RVG 118826
Clarithromycin Accord 500 mg film-coated tablets RVG 118827

This medicine is registered in EEA member states under the following names:

Country	Product name
Netherlands	Clarithromycin Accord 250 mg /500 mg film-coated tablets Austria Clarithromycin Accord 250 mg /500 mg Film tablets
Germany	Clarithromycin Accord 250 mg /500 mg Film tablets
Denmark	Clarithromycin Accord
Finland	Clarithromycin Accord 250 mg /500 mg tablet, film-coated Ireland Clarithromycin 250 /500 mg film-coated tablets
Italy	Claritromicina Accord
Norway	Clarithromycin Accord
Poland	Klabolic
Spain	Clarithromycin Accord 250 mg/500 mg film-coated tablets film
France	Clarithromycin Accord 250 mg/500 mg film-coated tablet

This leaflet was last approved in August 2025.