

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about CLARITHRO.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you using CLARITHRO against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine. You may need to read it again.

What CLARITHRO is used for

CLARITHRO is used to treat certain bacterial infections, including the following:

- respiratory tract infections
- skin infections
- peptic ulcer.

CLARITHRO is also used to prevent a specific bacterial infection associated with HIV infection.

Your doctor, however, may have prescribed CLARITHRO for another purpose.

Ask your doctor if you have any questions about why CLARITHRO has been prescribed for you.

CLARITHRO is an antibiotic that belongs to the group of medicines called macrolides. These medicines work by killing or stopping the growth of bacteria which cause infections.

CLARITHRO will not work against infections caused by viruses, such as colds or flu.

CLARITHRO is available only with a doctor's prescription.

CLARITHRO to treat peptic ulcer

Peptic ulcers are associated with an infection in the intestine and stomach caused by the bacteria *Helicobacter pylori* (*H. pylori*). Nearly all patients with peptic ulcers are infected with *H. pylori*.

The *H. pylori* infection can be treated with a combination of CLARITHRO (clarithromycin), another antibiotic (amoxicillin) and another medicine called omeprazole (used to control the acidity of the stomach).

However, the best combination of tablets to treat *H. pylori* infection is yet to be determined. Your doctor will determine the best combination for you.

If your symptoms return, consult your doctor.

It is possible that CLARITHRO may no longer be effective in killing the *H. pylori* infection and a different antibiotic may be needed.

Before you take CLARITHRO

When you must not take it

Do not take CLARITHRO if you are allergic to medicines containing clarithromycin or any other macrolide antibiotic (such as erythromycin, roxithromycin and azithromycin) or any

of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include rash, itching or hives, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or difficulty in breathing.

Do not take CLARITHRO if you have:

- severe liver problems
- poor kidney function.

Do not take CLARITHRO if you have an irregular heartbeat.

Do not take CLARITHRO if you have ever had a heart conditions called long QT syndrome (or QT prolongation).

Do not take CLARITHRO if you have low potassium levels.

Do not take CLARITHRO if the expiry date (Exp.) printed on the pack has passed.

Do not take CLARITHRO if the packaging shows signs of tampering or the tablets do not look quite right.

Do not take CLARITHRO if you are taking these medicines:

- astemizole or terfenadine (commonly used to treat allergy symptoms - these medicines may be available without a prescription)
- cisapride (Prepulsid), a medicine used to treat stomach disorders
- domperidone (used for nausea)
- pimozide (Orap), a medicine used to treat schizophrenia
- ergotamine (Cafergot) or dihydroergotamine (Dihydergot), medicines for headaches
- lovastatin or simvastatin (used to treat high cholesterol)
- ticagrelor or ranolazine (used to prevent blood clotting)
- colchicine (used to treat gout)
- midazolam tablets or syrup (used to treat sleeplessness and anxiety).

Taking CLARITHRO with any of the above medicines may cause serious side effects.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you are pregnant or plan to become pregnant.

Your doctor will discuss the risks and benefits of taking CLARITHRO during pregnancy.

Tell your doctor if you are breastfeeding or wish to breastfeed.

Your doctor will discuss the risks and benefits of taking CLARITHRO when breastfeeding.

Tell your doctor if you have, any medical conditions, especially the following:

- heart problems, including slow heart rate
- liver problems
- poor kidney function
- myasthenia gravis (a condition where the muscles become weak or tire easily)

- intolerance to sugars
- low magnesium or any other electrolyte imbalances.

Your doctor may want to take special care if you have any of these conditions.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking or are given CLARITHRO.

Taking other medicines

Tell your doctor if you are taking any other medicines, including those you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may affect how CLARITHRO works or may be affected by CLARITHRO. These include medicines already listed under "When you must not take CLARITHRO" (see above) and the following medicines:

- digoxin, quinidine, disopyramide (used to treat heart failure)
- warfarin and other anticoagulants (used to prevent blood clotting)
- phenytoin, carbamazepine, phenobarbital (phenobarbitone), sodium valproate (used to treat epilepsy)
- theophylline (used to treat asthma)
- triazolam, alprazolam, midazolam (used to treat sleeplessness and anxiety)
- cilostazol (used to treat poor circulation)
- statins such as rosuvastatin, atorvastatin (used to treat high cholesterol)
- methylprednisolone, a corticosteroid
- vinblastine (used to treat cancer)
- sildenafil, tadalafil, vardenafil (used to treat erectile dysfunction in adult males)
- ciclosporin, tacrolimus (medicines affecting the immune system)
- medicines used to treat HIV infection
- rifabutin, rifampentine, rifampicin (used to treat infections)
- repaglinide, nateglinide, pioglitazone (used to treat diabetes)
- insulin (used to treat diabetes)
- calcium channel blockers such as verapamil, amlodipine, diltiazem (used to treat high blood pressure)
- fluoxetine (used to treat depression)
- omeprazole (used to treat stomach problems)
- aminoglycosides (used to treat infections)
- fluconazole and itraconazole (used to treat fungal infections)
- tolterodine (used to treat bladder problems)
- herbal medicines such as St John's Wort
- quetiapine (used in psychotic disorders)
- ibrutinib (used in cancer therapy).

These medicines may be affected by CLARITHRO or may affect how well CLARITHRO works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor can tell you what to do if you are taking any of these medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking CLARITHRO.

How to take it

How much to take

The dose of CLARITHRO will depend on the infection to be treated.

For respiratory tract infections and skin infections, the usual adult dose is one CLARITHRO 250 mg tablet twice a day.

For more severe infections, the dose can be increased to two CLARITHRO tablets twice a day.

Your doctor will adjust the amount or frequency of your doses according to the infection being treated and the severity of your condition.

Follow all directions given to you by your doctor and pharmacist carefully.

How to take CLARITHRO

CLARITHRO tablets should be swallowed whole with a glass of water.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally. Do not take a double dose to make up for the dose you missed.

If you are not sure what to do, ask your doctor or pharmacist.

How long to take it for

Keep taking CLARITHRO until you finish the pack or for as long as your doctor tells you.

If you are being treated for an infection, CLARITHRO is usually taken for one or two weeks.

Do not stop taking CLARITHRO, even if you feel better after a few days, unless advised by your doctor.

Your infection may not clear completely if you stop taking your medicine too soon.

Check with your doctor if you are not sure how long you should be taking CLARITHRO.

If you take too much CLARITHRO (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much CLARITHRO. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much CLARITHRO, you may develop severe gastrointestinal symptoms, liver problems, or allergic reactions.

While you are taking CLARITHRO

Things you must do

If you are taking CLARITHRO for an infection and your symptoms do not improve within a few days, or if they become worse, tell your doctor.

Tell your doctor if you become pregnant while taking CLARITHRO.

If you get severe diarrhoea, tell your doctor or pharmacist immediately.

Do this even if it occurs several weeks after stopping CLARITHRO. Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care. Do not take any medicine to stop your diarrhoea without first checking with your doctor.

Tell your doctor immediately if you experience any heart palpitations, changes in heartbeat, dizziness or fainting while taking CLARITHRO.

If you have to have any urine tests, tell your doctor you are taking CLARITHRO as it may affect the results of some laboratory tests.

Before starting any new medicine, tell your doctor or pharmacist that you are taking CLARITHRO.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking CLARITHRO.

Things you must not do

Do not use CLARITHRO to treat any other conditions unless your doctor tells you to.

Do not give CLARITHRO to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how CLARITHRO affects you.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking CLARITHRO.

CLARITHRO treats infections in most people, but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

While you are taking CLARITHRO

Tell your doctor if you notice any of the following and they worry you:

- stomach cramps and pains
- nausea, vomiting, and severe diarrhoea
- oral thrush (sore white mouth or tongue) or vaginal thrush (vaginal itching or discharge)
- change in taste sensation
- headache
- asthma, shortness of breath
- muscle weakness, pain, or spasms
- conjunctivitis
- chills
- fatigue
- eructation
- stomach distension
- flatulence

Tell your doctor immediately if you notice any of the following as you may need urgent medical care:

- yellowing of the eyes or skin (jaundice)
- feeling generally unwell and having poor appetite
- hearing disturbances
- chest pain
- dizziness, confusion, hallucinations, convulsions
- fainting, irregular heartbeat
- any type of skin rash, itching, hives
- severe diarrhoea, especially if bloody
- severe upper stomach pain, with nausea and vomiting (pancreatitis).

These are serious side effects. You may need urgent medical treatment.

Stop taking CLARITHRO and tell your doctor immediately, or go to Accident and Emergency at the nearest hospital:

- swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing, shortness of breath or sudden collapse.

After using CLARITHRO

Tell your doctor immediately if you notice any of the following side effects, even if they occur several weeks after stopping treatment with CLARITHRO:

- severe stomach or abdominal cramps
- watery and severe diarrhoea, which may also be bloody (this may occur several weeks after you stop CLARITHRO)
- fever, in combination with one or both of the above.

These are rare but serious side effects. You may have a serious condition affecting your bowel and you may need urgent medical care.

Do not take any diarrhoea medicine without first checking with your doctor.

Other side effects not listed above may also occur in some patients. Ask your doctor or pharmacist for more information about side effects, as they have a more complete list of side effects. Inform your doctor promptly about these or any other symptoms. If the condition persists or worsens, seek medical attention.

Do not be alarmed by this list of possible side effects. You may not experience any of them or only some of them.

Tell your doctor if you notice anything that is making you feel unwell while you are taking, or soon after you have finished taking CLARITHRO, even if it is not on this list.

After using CLARITHRO

Storage

Keep CLARITHRO where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep CLARITHRO in a cool dry place, protected from light, where the temperature stays below 25°C.

Do not store CLARITHRO or any other medicine in the bathroom or near a sink.

Do not leave CLARITHRO in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop using CLARITHRO, or your medicine has passed its expiry date, ask your pharmacist what to do with any tablets that are left over.

Product description

What it looks like

CLARITHRO is a yellow, oval film-coated tablet.

Each blister pack contains 14 tablets.

Ingredients

The active ingredient in CLARITHRO is clarithromycin. Each CLARITHRO 250 tablet contains 250 mg of clarithromycin.

CLARITHRO tablets also contain:

- microcrystalline cellulose
- croscarmellose sodium
- pregelatinised maize starch
- povidone
- purified talc
- magnesium stearate
- colloidal anhydrous silica
- Opadry II 40L22445 yellow.

Free from lactose, gluten, sucrose, tartrazine or other azo dyes.

Sponsor

Apotex Pty Ltd
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Australian registration numbers:
CLARITHRO 250 - AUST R 117197

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