

CLARITHRO

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking CLARITHRO?

CLARITHRO contains the active ingredient clarithromycin. CLARITHRO is used to treat certain bacterial infections including respiratory tract infections, ear infections, skin infections and peptic ulcer. CLARITHRO is also used to prevent a specific bacterial infection associated with HIV infection. For more information, see Section [1. Why am I taking CLARITHRO?](#) in the full CMI.

2. What should I know before I take CLARITHRO?

Do not take if you have ever had an allergic reaction to clarithromycin, other antibiotics from the macrolide family or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I take CLARITHRO?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with CLARITHRO and affect how it works or may be affected by CLARITHRO. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take CLARITHRO?

Your doctor will tell you how much to take and when to take it. Take CLARITHRO exactly as directed by your doctor. More instructions can be found in Section [4. How do I take CLARITHRO?](#) in the full CMI.

5. What should I know while taking CLARITHRO?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are taking CLARITHRO.Tell your doctor if you are taking CLARITHRO for an infection and your symptoms do not improve within a few days, or they become worse, you become pregnant, you get severe diarrhoea, you experience heart palpitations, changes in heartbeat, dizziness or fainting or you are having urine tests.
Things you should not do	<ul style="list-style-type: none">Do not take CLARITHRO to treat any other complaints unless your doctor says so.Do not give this medicine to anyone else, even if their symptoms seem similar to yours.
Driving or using machines	<ul style="list-style-type: none">Be careful driving or operating machinery until you know how CLARITHRO affects you.
Looking after your medicine	<ul style="list-style-type: none">Keep CLARITHRO tablets in a cool dry place below 25°C and protected from light.

For more information, see Section [5. What should I know while taking CLARITHRO?](#) in the full CMI.

6. Are there any side effects?

Tell your doctor if you experience any of the following: stomach cramps and pains, nausea, vomiting and diarrhoea, oral thrush or vaginal thrush, change in taste sensation, headache, asthma, shortness of breath, muscle weakness, pain or spasms, conjunctivitis, chills, fatigue, eructation (belching), stomach distension or 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, 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 or severe upper stomach pain, with nausea and vomiting. **Stop taking CLARITHRO and call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects:** swelling to the face, lips, mouth, throat or neck which may cause difficulty in swallowing or breathing or sudden collapse.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

CLARITHRO

Active ingredient: *clarithromycin*

Consumer Medicine Information (CMI)

This leaflet provides important information about using CLARITHRO. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking CLARITHRO.**

Where to find information in this leaflet:

- [1. Why am I taking CLARITHRO?](#)
- [2. What should I know before I take CLARITHRO?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take CLARITHRO?](#)
- [5. What should I know while taking CLARITHRO?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I taking CLARITHRO?

CLARITHRO contains the active ingredient clarithromycin, 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 used to treat certain bacterial infections, including the following:

- **respiratory tract infections (throat, airways and lungs)**
- **ear 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 to treat peptic ulcer

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

The *H. pylori* infection can be treated with a combination of CLARITHRO (clarithromycin) and other appropriate antibiotic and stomach acid control treatments. 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.

2. What should I know before I take

Warnings

Do not take CLARITHRO if:

- you are allergic to clarithromycin, other antibiotics from the macrolide family, including erythromycin, roxithromycin or azithromycin or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can take this medicine.
- you have severe liver problems and poor kidney function.
 - you have an irregular heartbeat.
 - you have ever had a heart condition called long QT syndrome (or QT prolongation).
 - you have low magnesium or potassium levels.
 - you are taking any of the following medicines:
 - astemizole or terfenadine (commonly used to treat allergy symptoms - these medicines may be available without a prescription)
 - cisapride (used to relieve certain stomach problems)
 - colchicine (used to treat gout)
 - domperidone (used for nausea)
 - ergotamine or dihydroergotamine (used to treat headaches)
 - lomitapide (used to treat high cholesterol)
 - lovastatin or simvastatin (used to treat high cholesterol)
 - midazolam tablets or syrup (used to treat sleeplessness and anxiety)
 - pimozide (used to treat schizophrenia)
 - ticagrelor or ranolazine (used to prevent blood clotting)

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.

Do not take CLARITHRO after the expiry date or if the packaging is torn or shows any signs of tampering.

If it has expired or is damaged return it to your pharmacist for disposal.

Check with your doctor if you have:

- any other medical conditions or take any medicines for any other condition
- allergies to any other medicines, foods, dyes or preservatives
- heart problems, including slow heart rate
- liver problems
- poor kidney function
- myasthenia gravis, a condition which the muscles become weak and tire easily
- intolerance to sugars
- any 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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. Your doctor will discuss the risks and benefits of taking CLARITHRO when pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Your doctor will discuss the risks and benefits of taking CLARITHRO when breastfeeding.

3. What if I am taking other medicines?

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

Some medicines may interfere with CLARITHRO and affect how it works or may be affected by CLARITHRO. These include the medicines already listed under "Do not take CLARITHRO if" (see above) and the following medicines:

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

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

Your doctor or pharmacist can tell you what to do if you are taking any of these medicines. They also have a more complete list of medicines to be careful with or avoid while taking CLARITHRO.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect CLARITHRO.

4. How do I take CLARITHRO?

How much to take

- Your doctor will tell you how much to take and when to take it. Take CLARITHRO exactly as directed by your doctor. This may differ from the information contained in this leaflet.
- **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 250 mg tablet 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.
- **If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.**

How to take CLARITHRO

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

When to take CLARITHRO

- CLARITHRO should be taken at about the same time each day.
- This will allow your medicine to have the best effect and help you remember to take it.
- The prepared suspension can be taken with or without meals and can be taken with milk.

How long to take it

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 forget to take CLARITHRO

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 it as soon as you remember, and then continue taking your medicine as you would normally.

Do not take a double dose to make up for the dose you missed.

If you miss more than one dose, are not sure what to do, or have any questions, check with your doctor or pharmacist.

If you take too much CLARITHRO

If you think that you have taken too much CLARITHRO, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

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

5. What should I know while taking

Things you should 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.

Call your doctor straight away if you:

- **get severe diarrhoea.** 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.
- **experience any heart palpitations, changes in heartbeat, dizziness or fainting while taking CLARITHRO.**

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

If you are about to start taking a new medicine, tell your doctor or pharmacist that you are taking CLARITHRO.

Remind any doctor, dentist or pharmacist you visit that you are taking CLARITHRO.

Things you should not do

- Do not take CLARITHRO to treat any other complaints unless your doctor says so.

- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how CLARITHRO affects you.

Looking after your medicine

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack, they will not keep well.

Keep it where young children cannot reach it. A locked cupboard at least 1.5 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 it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

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

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects. Do not be alarmed by this list of possible side effects. You may not experience any of them.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• stomach cramps and pains• nausea, vomiting and 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 (belching)• stomach distension (bloating)• flatulence	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• 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)	Tell your doctor straight away if you notice any of these symptoms as you may need urgent medical care.
<ul style="list-style-type: none">• swelling to the face, lips, mouth, throat or neck which may cause difficulty in swallowing or breathing or sudden collapse	Stop taking CLARITHRO and call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

After you have finished taking 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 taking 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. Tell your doctor about these or any other symptoms. If the condition persists or worsens, seek medical attention.

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.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What CLARITHRO Tablet contains

Active ingredient (main ingredient)	Each CLARITHRO 250 mg tablet contains 250 mg of clarithromycin.
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• microcrystalline cellulose• croscarmellose sodium• pregelatinised maize starch• povidone• purified talc• magnesium stearate• colloidal anhydrous silica• Opadry II 40L22445 yellow

Do not take this medicine if you are allergic to any of these ingredients.

What CLARITHRO looks like

CLARITHRO 250 mg tablets are yellow, oval, film-coated tablets.

Each blister pack contains 14 tablets (AUST R 117197).

Who distributes CLARITHRO

Apotex Pty Ltd
16 Giffnock Avenue
Macquarie Park NSW 2113

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