

Apo-Clarithromycin

Contains the active ingredient, clarithromycin (kla-RITH-roë-mye-sin)

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine .

Ask your doctor or pharmacist if you do not understand anything or are worried about taking your medicine.

This leaflet answers some common questions about clarithromycin.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. Some more recent information on your medicine may be available. Speak to your pharmacist or doctor to obtain the most up-to-date information.

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

Keep this leaflet with your medicine.

You may want to read it again.

What Clarithromycin is used for

The name of your medicine is Apo-Clarithromycin. It contains the active ingredient, clarithromycin.

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

- Infections of the respiratory tract
- Skin infections
- Peptic ulcer

How it works

This medicine is an antibiotic that belongs to the group of medicines macrolides. These medicines work by killing or stopping the growth of bacteria which causes infections.

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

Your doctor may have prescribed it for another reason.

This medicine will not work against infection caused by viruses, such as cold or flu.

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

There is no evidence that this medicine is addictive.

This medicine is not expected to affect your ability to drive a car or operate machinery, but make sure you know how it affects you before driving.

Use in children

These tablets are not recommended for children under 12 years of age.

Before you take Clarithromycin

When you must not take it

Do not take this medicine if:

1. You have ever had an allergic reaction to any medicine containing Clarithromycin or to other antibiotics from the macrolide family. These may include :
 - erythromycin
 - roxithromycin
 - azithromycin
 - clindamycin
 - lincomycin
2. You are allergic to any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include: shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; muscle pain or tenderness or joint pain; or rash, itching or hives on the skin.

3. You are taking any of the following medicines:
 - cisapride, a medicine used to treat stomach problems
 - pimozide, a medicine used to treat psychotic disorders
 - antihistamine medicines, such as terfenadine
 - medicines such as ergotamine or dihydroergotamine, used to treat migraines (e.g. Cafergot).

4. Your doctor may decide that you should not take this medicine if your potassium or magnesium levels are too low or your kidneys are not working properly, or you have serious heart problems.

Do not take this medicine after the expiry date (EXP) printed on the pack.

If you take this medicine after the expiry date has passed, it may not work as well.

Do not take this medicine if the packaging is torn, shows signs of tampering or if it does not look quite right.

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

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

Before you start to take it

Tell your doctor if:

1. You have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

2. You have or have had any medical conditions, especially the following:

- **Severe liver problems**
- **Poor kidney function**
- Low potassium or magnesium
- Serious heart problems
- Myasthenia Gravis, a disease of the muscles causing drooping eyelids, double vision, difficulty in speaking and swallowing and sometimes muscle weakness in the arms or legs.

3. You plan to become pregnant or breast-feed.

This medicine may affect the development of your unborn baby, and also passes into breast milk, so there is a possibility that your baby may be affected. Your doctor can discuss with you the risks and benefits of taking this medicine.

If you have not told your doctor about any of the above, tell them before you start taking this medicine.

Taking other medicines

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

Some medicines must not be taken with clarithromycin. These include:

- cisapride
- pimozide
- terfenadine
- ergotamine or dihydroergotamine (e.g. Cafergot).

Some medicines and clarithromycin may interfere with each other. These include:

- medicines used to prevent blood clotting, such as warfarin
- some medicines used for epilepsy such as phenytoin, valproate, carbamazepine and hexobarbital
- theophylline, a medicine used to treat asthma
- digoxin, quinidine and disopyramide, used to treat heart complaints
- medicines used to treat sleeplessness such as triazolam or midazolam
- alprazolam, used to treat anxiety
- anti-viral medicines such as zidovudine, ritonavir, indinavir, atazanavir, saquinavir, efavirenz and nevirapine
- rifampicin and rifabutin, types of antibiotics
- itraconazole and ketoconazole, used to treat fungal infections
- fluoxetine, used for treating depression
- colchicine, used to treat gout
- sildenafil, tadalafil, vardenafil, used to treat erection problems
- vinblastine, used to treat certain cancers

- cyclosporin, tacrolimus, used for eczema and in organ transplants
- cilostazol, used to help circulation and stop blood clots
- methylprednisolone, a corticosteroid used for reducing inflammation in various medical conditions
- simvastatin, lovastatin, used for lowering cholesterol
- omeprazole, used in treating stomach ulcers
- tolterodine, used to treat urinary incontinence
- repaglinide, used to treat diabetes
- cabergoline, used for treating Parkinson's Disease.

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

Your doctor and pharmacist will advise you. They will tell you if you are taking any of these medicines. They may also have more information on other medicines to be careful with or avoid while taking clarithromycin.

Other interactions not listed above may also occur.

How to take this medicine

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

They may be different to the information in this leaflet.

If you do not understand any written instructions, ask your doctor or pharmacist for help.

How much to take

Your doctor or pharmacist will tell you how much you will need to take. This depends on your condition and whether or not you are taking any other medicines.

For respiratory tract infections and skin infections, the usual adult dose is one clarithromycin 250 mg tablet taken twice a day. The dose may be higher in other infections.

How to take it

Swallow the tablet whole with a full glass of water.

When to take it

Take it at about the same time each day.

Taking your medicine at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take it before, with or after food.

How long to take it for

Continue taking your medicine until you finish all the prescribed tablets, or until your doctor tells you to stop taking it.

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

Do not stop taking Clarithromycin, 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 clarithromycin.

Make sure you have enough to last over weekends and holidays.

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 it as soon as you remember, and then go back to taking your medicine as you would normally.

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

This may increase the chance of you getting an unwanted side effect.

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

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 for Australia) for advice, or go to the Accident and Emergency Department at the nearest hospital, if you think that you or anyone else may have taken too much clarithromycin.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much clarithromycin, you may develop severe stomach or liver problems.

While you are taking clarithromycin

Things you must do

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

If you become pregnant while taking this medicine, tell your doctor immediately.

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

Do this even if it occurs several weeks after stopping clarithromycin. 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.

If you get a sore white mouth or tongue while taking or soon after stopping clarithromycin, tell your

doctor. Also tell your doctor if you get vaginal itching or discharge.

This may mean you have a fungal infection called thrush. Sometimes the use of this medicine allows fungi to grow and the above symptoms to occur.

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking clarithromycin.

If you are about to have any blood or urine tests, tell your doctor that you are taking clarithromycin as it may affect the results of some laboratory tests.

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

Go to your doctor regularly for a check-up.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects.

Things you must not do

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

Do not take your medicine to treat any other complaints unless your doctor or pharmacist tells you to.

Do not stop taking your medicine, or change the dosage, without checking with your doctor, even if you feel better in a few days.

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

Things to be careful of

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

Side effects of clarithromycin

All medicines may have some unwanted side effects. Sometimes they are serious, but most of the time,

they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

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

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

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

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

- feeling or being sick, mild diarrhoea, constipation or mild stomach pain
- heartburn, wind or indigestion
- dry or sore mouth
- sore or discoloured tongue
- discoloured teeth
- oral thrush or vaginal thrush
- strange taste or smell sensations
- headache
- problems sleeping, strange dreams
- feeling shaky or restless
- low blood sugar
- feeling depressed, nervous or anxious
- unusual tiredness or weakness
- flushing
- aversion to light
- body aches and pains
- back pain
- stained fingernails

Tell your doctor as soon as possible if you notice any of the following:

- feeling generally unwell and having a poor appetite
- changes in your liver
- fever, infection or ear pain
- hearing disturbances, ringing in the ears

- feeling dizzy, giddy, confused or disorientated, or seeing, feeling or hearing things that are not there.
- any type of skin rash, itching, or hives
- blood stained stools
- bleeding gums
- pain or burning when urinating
- dark, bloody or cloudy urine.

These may be serious side effects. You may need medical attention.

If any of the following happen, stop taking your medicine and either tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- wheezing or difficulty breathing
- palpitations, or fast or irregular heart beats
- any type of severe stomach pain
- severe watery or bloody diarrhoea
- yellowing of the skin or eyes (jaundice)
- swelling to the face, lips, mouth, throat or neck which may cause difficulty in swallowing or breathing or sudden collapse.
- severe skin rashes or blistering
- chest pain
- psychotic reaction (acting strangely)
- fits (convulsions or seizures).

These are very serious side effects. You may need urgent medical attention or hospitalisation.

Other side effects not listed above may occur in some patients.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

After finishing it

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

- severe abdominal cramps or stomach cramps

- watery and severe diarrhoea, which may also be bloody
- fever, in combination with one or both of the above.

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

You may have a serious condition affecting your bowel, and may therefore need urgent medical attention. However, this side effect is rare.

After taking this medicine

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take the tablets out of their original packaging they may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 30°C.

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

Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it 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.

Disposal

If your doctor or pharmacist tells you to stop taking this medicine or it has passed its expiry date, ask your pharmacist what to do with any medicine that is left over.

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical

advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

and APOTEX from the registered proprietor, Apotex Inc.

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Product description

What Apo-Clarithromycin looks like

Apo-Clarithromycin 250 mg tablets:

Pale yellow, oval, film-coated tablets engraved "CLA250" on one side, "APO" on the other side.

Available in:

Blister packs of 14 tablets.

Ingredients

Each tablet contains 250 mg of clarithromycin as the active ingredient.

It also contains the following inactive ingredients:

- microcrystalline cellulose
- croscarmellose sodium
- magnesium stearate
- colloidal anhydrous silica
- hypromellose
- iron oxide yellow E172
- titanium dioxide E171
- macrogol 8000.

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and other azo dyes-free.

Australian Registration Numbers

Apo-Clarithromycin 250 mg

Blister packs:

AUST R 134850

Sponsor

Apotex Pty Ltd

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Australia

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