

APO-Clarithromycin

Contains the active ingredient, clarithromycin (*kla-RITH-roe-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.

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. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up-to-date leaflet from www.apotex.com.au.

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.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

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

What this medicine 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

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

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 is available only with a doctor's prescription.

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.

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

There is no evidence that this medicine is addictive.

Use in children

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

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You have or have had any of the following:**
 - irregular heartbeat, including Torsades de pointes
 - severe liver problems in combination with kidney problems
 - liver or kidney problems and are taking a p-glycoprotein inhibitor or a strong CYP3A4 inhibitor (check with your doctor)
 - hypokalaemia (low potassium).
 - **You are hypersensitive to, or have had an allergic reaction to, clarithromycin, other antibiotics from the macrolide family or any of the ingredients listed at the end of this leaflet.**
 - Other macrolide antibiotics include:**
 - erythromycin
 - roxithromycin
 - azithromycin
 - Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.
 - If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.**
 - **You are taking any of the following medicines:**
 - astemizole or terfenadine (commonly used to treat allergy symptoms - these medicines may be available without prescription)
 - cisapride, a medicine used to treat stomach problems
 - pimozide, a medicine used to treat psychotic disorders
 - ergotamine or dihydroergotamine, used to treat migraines
 - lovastatin or simvastatin, used to treat high cholesterol
 - midazolam
 - ticagrelor or ranolazine
 - **The expiry date (EXP) printed on the pack has passed.**
 - **The packaging is torn, shows signs of tampering or it does not look quite right.**
3. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.
 4. You are currently breastfeeding or you plan to breastfeed. Do not take this medicine whilst breastfeeding until you and your doctor have discussed the risks and benefits involved.
 5. You are planning to have surgery or an anaesthetic.
 6. You are currently receiving or are planning to receive dental treatment.
 7. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with clarithromycin. 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
- alprazolam, used to treat anxiety
- anti-viral medicines such as zidovudine, ritonavir, indinavir, atazanavir, saquinavir, efavirenz, nevirapine and etravirine
- 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
- atorvastatin, rosuvastatin, used for lowering cholesterol
- omeprazole, used in treating stomach ulcers
- tolterodine, used to treat urinary incontinence
- medicines used to treat diabetes, such as insulin, repaglinide, nateglinide, pioglitazone and rosiglitazone
- calcium channel blockers used to treat high blood pressure, such as verapamil, amlodipine, diltiazem
- herbal medicines such as St John's Wort
- aminoglycosides, type of antibiotic

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with clarithromycin.

How to take this medicine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

How much to take

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

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

For more severe infections, the dose may be increased.

For respiratory tract infections, the usual dose for children is 7.5 mg/kg twice a day.

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

Do not stop taking your medicine or change your dosage without first checking with your doctor.

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 for as long as your doctor tells you.

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 experiencing side effects.

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)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

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 problems, liver problems or experience an allergic reaction.

While you are taking this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breastfeed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

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 get severe diarrhoea, tell your doctor 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.

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.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. Go to your doctor regularly for a check-up.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor
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.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking clarithromycin or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor if you notice any of the following:

- stomach cramps and pains
- nausea, vomiting and severe diarrhoea
- oral thrush or vaginal thrush
- change in taste sensation
- headache

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

These may be serious side effects and you may need medical attention.

- yellowing of the eyes or skin (jaundice)
- feeling generally unwell and having poor appetite
- hearing disturbances
- chest pain
- dizziness, confusion, hallucinations, convulsions
- any type of skin rash, itching, hives
- severe diarrhoea, especially if bloody
- severe upper stomach pain with nausea and vomiting (pancreatitis)
- unexpected muscle pain, tenderness or weakness not caused by exercise.

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

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

These are 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 occur in some patients.

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

Allergic reactions

If you think you are having an allergic reaction to clarithromycin, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

Storage and disposal

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.

Product description

What APO-Clarithromycin looks like

- **250 mg tablets:**
Pale yellow, oval, film-coated tablets engraved "CLA250" on one side, "APO" on the other side.
Available in blister packs of 2, 14, 28 and 100 tablets.
Available in bottles of 14, 28 and 100 tablets.
- **500 mg tablets:**
Pale yellow, capsule-shaped, film-coated tablets engraved "CLA500" on one side, "APO" on the other side.
Available in blister packs of 3, 14, 20, 28, 42 and 100 tablets
Available in bottles of 14, 20, 28, 42 and 100 tablets

* Not all strengths, pack sizes and/or pack types may be available.

Ingredients

Each tablet contains 250 mg or 500 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 pack):
AUST R 134850
- APO-Clarithromycin 250 mg (bottle):
AUST R 134865
- APO-Clarithromycin 500 mg (blister pack):
AUST R 134856
- APO-Clarithromycin 500 mg (bottle):
AUST R 134883

Sponsor

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