

# APO-CLARITHROMYCIN TABLET

Contains the active ingredient clarithromycin

## Consumer Medicine Information

---

### What is in this leaflet

This leaflet answers some common questions about Apo-Clarithromycin. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Apo-Clarithromycin against the benefits it is expected to have for you.

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

**Keep this leaflet with the medicine.**

You may need to read it again.

---

### What this medicine is used for

Apo-Clarithromycin is used to treat certain bacterial infections, including the following:

- Respiratory tract infections
- Skin infections
- Ear infections
- Peptic ulcer

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

Your doctor, however, may have prescribed clarithromycin for another purpose. Ask your doctor if you have any questions about why clarithromycin has been prescribed for you.

Apo-Clarithromycin 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.

Apo-Clarithromycin will not work against infections caused by virus, such as colds or flu.

Apo-Clarithromycin is available only with a doctor's prescription.

### *Apo-Clarithromycin to treat peptic ulcer*

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

The *H. pylori* infection can be treated with a combination of clarithromycin and other appropriate antibiotic and stomach acid control treatments. Your doctor will determine the best combination for you.

If your symptoms return, consult your doctor. It is possible that clarithromycin may no longer be effective in killing the *H. pylori* infection and a different antibiotic may be needed.

### *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 Apo-Clarithromycin if you have an allergy to:**

- medicines containing clarithromycin
- other antibiotics from the macrolide family – these include: erythromycin, roxithromycin, azithromycin
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- skin rash
- itching
- shortness of breath or swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing

**Do not take Apo-Clarithromycin if you have severe liver or kidney problems.**

**Do not take Apo-Clarithromycin if you have an irregular heartbeat.**

**Do not take Apo-Clarithromycin if you have low potassium.**

**Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

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

**Do not take Apo-Clarithromycin if you are taking any of the following medicines:**

- astemizole or terfenadine, used to treat allergy symptoms
- cisapride, used to relieve certain stomach problems
- domperidone, used to treat nausea and vomiting
- pimozide, used to treat schizophrenia
- ergotamine or dihydroergotamine, used to treat headaches

- lovastatin or simvastatin, used to treat high cholesterol
- ticagrelor, used to prevent blood clotting
- ranolazine, used to treat angina
- colchicine, used to treat gout
- oral midazolam, used in sleep disorder and as a sedative.

**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 pregnant or plan to become pregnant.**

Your doctor can discuss with you the risks and benefits involved.

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

Your doctor will discuss the risks and benefits of taking Apo-Clarithromycin when breastfeeding.

**Tell your doctor if you have or have ever had any other health problems or medical conditions, including:**

- heart problems
- liver problems
- kidney problems
- low magnesium levels
- myasthenia gravis, a condition in which the muscles become weak and tire easily.

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

**If you have not told your doctor about any of the above, tell him/her before you start taking Apo-Clarithromycin.**

### *Taking other medicines*

**Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without prescription from your pharmacy,**

### **supermarket or health food shop.**

Some medicines and Apo-Clarithromycin may interfere with each other. These include:

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

These medicines may be affected by Apo-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 will advise you.

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

---

## **How to take this medicine**

---

**Take Apo-Clarithromycin exactly as your doctor has prescribed.**

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

They may differ from the information contained in this CMI.

**If you do not understand the instructions in this leaflet, ask your doctor or pharmacist for help.**

### *How much to take*

***The dose of Apo-Clarithromycin will depend on the infection to be treated.***

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

For more severe infections, the dose can be increased to 500 mg twice a day.

For respiratory tract infections, the usual dose for children is 7.5mg/kg twice a day or as directed by your doctor.

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 box/bottle,**

**ask your doctor or pharmacist for help.**

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 your medicine at about the same time each day, either morning or evening.

Taking it 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 this medicine before or after food.

***How long to take it***

Continue taking Apo-Clarithromycin until you finish the pack, or for as long as your doctor tells you.

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

Do not stop taking Apo-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 Apo-Clarithromycin.

***If you forget to take it***

If it is almost time for you to take 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 miss more than one dose, or 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 Poisons Information Centre - the telephone number in Australia is 131 126 and in New Zealand is 0800 POISON or 0800 764 766 - for advice or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much Apo-Clarithromycin.

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

You may need urgent medical attention.

---

**While you are taking this medicine**

---

***Things you must do***

If you are taking Apo-Clarithromycin 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 Apo-Clarithromycin.

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

Do this even if it occurs several weeks after stopping Apo-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 need to have any urine tests, tell your doctor you are taking Apo-Clarithromycin 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 Apo-Clarithromycin.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Apo-Clarithromycin.

***Things you must not do***

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

Do not give your medicine 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 this medicine affects you.

---

**Possible side effects**

---

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

Apo-Clarithromycin treat 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 the list of possible side effects.

You may not experience any of them.

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

***Tell your doctor if...***

**Ask your doctor or pharmacist for advice if you experience any of the following and they worry you:**

- stomach cramps and pains
- nausea, vomiting and diarrhoea
- oral thrush or vaginal thrush
- change in sense of taste
- headache
- increased sweating
- difficulty sleeping
- asthma, shortness of breath

**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
- palpitations, fast heart rate
- 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)

**Stop taking Apo-Clarithromycin and tell your doctor immediately or go to Accident and Emergency at your nearest hospital if any of the following happen:**

- swelling to the face, lips, mouth, throat or neck which may cause difficulty in swallowing or breathing, or sudden collapse.

**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.**

---

## After taking Apo-Clarithromycin

---

**Tell your doctor immediately if you notice any of the following side effects, even if they occur several weeks after stopping treatment with Apo-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 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.**

---

## Storage and disposal

---

### *Storage*

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

If you take your tablets out of the pack they may not keep as well.

**Keep your tablets in a cool dry place where the temperature stays below 30°C.**

**Do not store Apo-Clarithromycin or any other medicine in the bathroom or near a sink. Do not leave your medicines on a window sill or in the car.**

Heat and dampness can destroy some medicines.

**Keep Apo-Clarithromycin 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 tells you to stop taking Apo-Clarithromycin, or the tablets have passed their expiry**

**date, ask your pharmacist what to do with any medicine that is left over.**

---

## Product description

---

### *What it looks like*

#### **250mg Tablet:**

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

#### **500mg Tablet:**

Pale yellow, capsule-shaped, biconvex, film-coated tablets engraved "CLA500" on one side, "APO" on the other side.

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

### *Ingredients*

Each tablet contains 250mg & 500mg of clarithromycin as the active ingredient.

It also contains the following inactive ingredients:

- Hypromellose
- Iron oxide yellow
- Macrogol
- Titanium dioxide
- Colloidal silicon dioxide
- Croscarmellose sodium
- Magnesium stearate
- Microcrystalline cellulose

This medicine does not contain gluten and lactose.

### *Sponsor*

Apotex NZ Ltd.  
32 Hillside Road  
Wairau Valley  
AUCKLAND 0627

Telephone: (09) 444 2073

Fax: (09) 444 2951

E-mail:

NZcustomerservice@apotex.com

This leaflet was last updated in:

October 2018