

APO-Ciprofloxacin Tablets

Contains the active ingredient, ciprofloxacin hydrochloride

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 ciprofloxacin. 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 the 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 the medicine. You may want to read it again.

What is this medicine used for

The name of your medicine is APO-Ciprofloxacin. It contains the active ingredient, ciprofloxacin.

It is used to treat:

- urinary tract infections
- kidney and bladder infections
- bowel infections
- lung infections
- skin infections
- bone and joint infections
- prostate infections
- inhalation of anthrax

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

Your doctor may have prescribed this medicine for another reason.

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

How it works

This medicine works by killing the bacteria which cause these infections.

It will not work against viral infections such as colds or flu.

Ciprofloxacin belongs to a group of antibiotic medicines called quinolones.

There is no evidence that this medicine is addictive.

Use in children

This medicine is not recommended for use in children or pre-pubertal teenagers except for use in inhalational anthrax.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- You are taking a medicine called tizanidine (used for multiple sclerosis or spinal injuries)
- You are hypersensitive to, or have had an allergic reaction to, ciprofloxacin, other quinolone antibiotics, nalidixic acid or 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 or other parts of the body, muscle pain or tenderness or joint pain or rash, itching or hives on the skin.

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.

- **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.

- **The packaging is torn or 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 ciprofloxacin, talk to your doctor.

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:

- kidney disease
- brain disease or stroke
- epilepsy (seizures or fits)
- arrhythmias (fast or irregular heartbeats)

Ciprofloxacin may increase the risk of arrhythmias, especially in the elderly or patients with low potassium levels.

- myasthenia gravis (disease of the muscles causing drooping eyelids, double vision, difficulty in speaking and swallowing and sometimes muscle weakness in the arms or legs)
- liver disease
- tendon disorders with the use of quinolones (e.g. moxifloxacin, norfloxacin, nalidixic acid).

3. You are elderly or have previously taken corticosteroids such as prednisolone or cortisone, or have had problems with your tendons before, when taking quinolone medicines.

You may be at increased risk of swelling of or damage to the

tendons. Symptoms include pain, tenderness and sometimes restricted movement.

4. You are currently pregnant or plan to become pregnant.

Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.

5. You are currently breast feeding or plan to breast feed. Do not take this medicine whilst breastfeeding until you and your doctor have discussed the risks and benefits involved.

Ciprofloxacin passes into human breast milk and may affect your baby, so your doctor will discuss with you what to do.

6. You are planning to have surgery or an anaesthetic.

7. You are currently receiving or are planning to receive dental treatment.

8. 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 must not be taken with ciprofloxacin.

Do not take ciprofloxacin if you are taking tizanidine, used for multiple sclerosis or spinal injuries.

Other medicines also interact with ciprofloxacin. These include:

- certain anti-arrhythmics, antidepressants, antibiotics and antipsychotics
- theophylline, and other methylxanthines, medicines used to help breathing. Caffeine is also a methylxanthine.
- duloxetine, a medicine used for depression, incontinence or diabetic neuropathy
- cyclosporin, used in organ transplants, or for severe arthritis or psoriasis

- methotrexate, used to treat certain cancers, or for severe arthritis or psoriasis

- warfarin or other medicines called anticoagulants, used to prevent blood clots

- phenytoin, a medicine used to treat epilepsy

- anti-viral medications such as didanosine

- certain non-steroidal anti-inflammatory medicines (NSAIDs), used to treat muscular problems and arthritis. The combination of these medicines with ciprofloxacin may cause convulsions

- clozapine, a medicine used to treat schizophrenia

- ropinirole, used to treat restless legs syndrome

- lidocaine, used in certain heart conditions and for local or spinal anaesthesia

- sildenafil, a medicine used to treat erectile dysfunction

- medicines containing iron, zinc, magnesium, aluminium or calcium such as antacids, multivitamins or mineral supplements

- probenecid, used for gout, arthritis, or to raise levels of antibiotics

- omeprazole, a medicine used to treat stomach ulcers.

- sucralfate, a medicine used to treat stomach ulcers

- metoclopramide, used to treat nausea and vomiting

- oral anti-diabetic agents such as glibenclamide and glimepiride

- antiretroviral medicines such as didanosine, used to treat HIV infections

- medicines such as sevelamer, used to treat high blood levels of phosphate

- oxpentifylline, used to treat circulation disorders

- agomelatine, used to treat depression
- zolpidem, used to treat sleep disorders

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 ciprofloxacin.

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.

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

How much to take

Your doctor will tell you how many tablets you will need to take. This will depend on your condition and whether or not you are taking any other medicines.

The usual adult dosage for most infections is one tablet twice daily for 7 to 14 days. You may need to take your tablets for a longer period for some infections.

How to take it

Swallow the tablets whole with a full glass of water.

When to take it

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

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

If you need to take an antacid, take it at least 2 hours before or 2 hours after your dose of ciprofloxacin.

How long to take it for

The length of treatment may vary from 1 to 28 days or longer depending on the type of infection.

Continue taking your medicine until you finish the pack or for as long as your doctor tells you.

Do not stop taking your tablets because you are feeling better.

If you do not complete the full course prescribed by your doctor, the infection may not clear completely or your symptoms may return.

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

If you forget to take it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time.

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 missed doses.

This may increase the chance of you experiencing side effects.

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) 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 ciprofloxacin.

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

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 are going into hospital.

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.

Drink plenty of water or fluids while taking this medicine.

This will help to prevent crystals forming in the urine which can cause kidney problems. However, this is not a common problem.

Protect your skin when you are in the sun, especially between 10 am and 3 pm, or in the presence of artificial ultraviolet (UV) light. Wear protective clothing and use a 15+ sunscreen. If your skin does appear to be burning, stop taking this medicine and tell your doctor.

Ciprofloxacin may cause your skin to be much more sensitive to sunlight and UV light than it is normally. This may cause a skin rash, itching, redness, or a severe sunburn.

Things you must not do

Do not:

Give this medicine to anyone else, even if their symptoms seem similar to yours.

- 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.

If you do not complete the full course prescribed by your doctor, all of the bacteria causing your infection may not be killed. These bacteria may continue to grow and multiply so that your infection may not clear completely or it may return and be more difficult to treat.

Things to be careful of

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

This medicine may cause dizziness, light-headedness or drowsiness in some people, or may change your reaction time. If you have any of these symptoms, do not drive or operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while you are taking this medicine.

If you drink alcohol, dizziness, light-headedness or drowsiness may be worse.

Be careful when drinking beverages containing caffeine (e.g. coffee, cola drinks) while you are taking this medicine.

Ciprofloxacin tablets may increase the stimulatory effects of caffeine.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking ciprofloxacin or if you have 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:

- nausea, vomiting, mild diarrhoea
- loss of appetite
- mild stomach pain or wind
- agitation, anxiety or restlessness
- sleeping disorders
- headache
- dizziness or light-headedness
- tremor, twitching or weakness
- purple or red spots on the skin
- strange taste, smell or touch sensations.

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.

- vaginal itching or discharge
- a sore white mouth or tongue
- altered vision (specialist consult needed)
- migraine
- difficulty walking, uncoordinated, shaking
- getting sunburnt very easily
- joint or muscle pain, muscle cramps, or inflamed, painful or ruptured tendons such as the Achilles tendon
- tinnitus (ringing in the ears), problems with hearing
- symptoms of hypoglycaemia (low blood sugar) e.g. sweating, weakness, dizziness, trembling, headache, and having a fast, pounding heartbeat
- symptoms of hyperglycaemia (high blood sugar): feeling hungry, thirsty and/or frequent or excessive urination
- a worsening of the symptoms of myasthenia gravis, e.g. weaker muscles which tire more easily, drooping eyelids, double vision, difficulty in speaking and swallowing

- confusion, hallucinations, depression.

In isolated instances, some serious side effects may be long-lasting (more than 30 days) and disabling, such as tendonitis, tendon rupture, musculoskeletal disorders and other reactions affecting the nervous system including mental health disorders and disturbance of senses.

If you experience any of the following, stop taking your medicine and either tell your doctor immediately or go to Accident and Emergency at your nearest hospital: These are very serious side effects. You may need urgent medical attention or hospitalisation.

- severe watery or bloody diarrhoea, even if it occurs several weeks after you have stopped taking this medicine
- severe stomach pains
- severe skin rashes or blistering
- numbness, pain, burning, tingling or pins and needles in outer limbs
- palpitations, or fast or irregular heart beats
- chest pain
- fainting
- dark, bloody or cloudy urine
- yellowing of the skin or eyes (jaundice)
- fits (convulsions or seizures)
- confusion, nightmares, hallucinations and psychotic reaction (even progressing to self-endangering behaviour)
- ringing in the ear, loss of hearing
- visual disturbances

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

Allergic reactions

If you think you are having an allergic reaction to ciprofloxacin, 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:

- 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.

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 ciprofloxacin:

- 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.

Storage and disposal

Storage

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

If you take your medicine out of its original packaging they may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°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 on hot days. 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 tells you to stop taking this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Ciprofloxacin looks like

- 250 mg - white to off-white, round, film-coated tablets marked with "250" on one side and plain on the other.

Blister packs of 14 tablets

- 500 mg - white to off-white, caplet (oval) shaped, film-coated tablets marked with "500" on one side and plain on the other.\

Blister packs of 14 tablets

- 750 mg - white to off-white, caplet (oval) shaped, film-coated tablets marked with "750" on one side and plain on the other.

Blister packs of 14 tablets

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

Ingredients

Each tablet contains 250 mg, 500 mg or 750 mg of ciprofloxacin.

It also contains the following inactive ingredients:

- microcrystalline cellulose
- maize starch
- magnesium stearate
- purified talc
- colloidal anhydrous silica
- sodium starch glycollate type A
- purified water
- hypromellose

- titanium dioxide
- macrogol 400.

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

Australian Registration Numbers

APO-Ciprofloxacin 250mg Tablets

AUST R Number 135650

APO-Ciprofloxacin 500mg Tablets

AUST R Number 135651

APO-Ciprofloxacin 750mg Tablets

AUST R Number 135652

Sponsor

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