

GenRx Ciprofloxacin

Contains the active ingredient, ciprofloxacin hydrochloride

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

Consumer Medicine Information

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 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. Speak to your pharmacist or doctor to obtain the most up to date information on the medicine.

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 the medicine.

You may want to read it again.

What Ciprofloxacin is used for

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

It is used to treat:

- * kidney and bladder infections
- * bowel infections
- * lung infections
- * skin infections
- * bone and joint infections
- * prostate infections.

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 (pronounced KWIN-a-lones).

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

Your doctor may have prescribed ciprofloxacin for another reason.

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

There is no evidence that this medicine is addictive.

This medicine may affect your ability to drive a car or operate machinery, so make sure you know how it affects you before driving.

Use in children

This medicine is not recommended for use in children or growing teenagers.

Before you take Ciprofloxacin

When you must not take it

Do not take this medicine if you have had an allergic reaction to:

- * ciprofloxacin
- * any of the ingredients listed at the end of this leaflet
- * any other quinolone antibiotics such as norfloxacin, ofloxacin or nalidixic acid.

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.

Do not take this medicine if you are taking a medicine called tizanidine (used for multiple sclerosis or spinal injuries)

You may have more chance of side effects such as low blood pressure, sleepiness and drowsiness.

Do not take this medicine if you are breast feeding.

Ciprofloxacin passes into human breast milk and may affect your baby.

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 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 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:

- * kidney disease
- * brain disease or stroke
- * epilepsy (seizures or fits)
- * 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.

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 pregnant or plan to become pregnant.

Your doctor will discuss with you the risks and benefits of taking this whilst pregnant.

5. You are breast feeding or plan to breast feed.

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

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

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 and ciprofloxacin may interfere with each other. These include:

- * theophylline and other methylxanthines, medicines used to help breathing. Caffeine is also a methylxanthine.
- * duloxetine, a medicine used for depression, incontinence or diabetic neuropathy
- * probenecid, used for gout, arthritis, or to raise levels of antibiotics
- * 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
- * glibenclamide, tablets used to treat diabetes
- * certain non-steroidal anti-inflammatory medicines, used to treat muscular problems and arthritis. The combination of these medicines with ciprofloxacin may cause convulsions.
- * tizanidine, used for multiple sclerosis or spinal injuries - see "When you must not take it"
- * ropinirole, used to treat restless legs syndrome
- * lidocaine, used in certain heart conditions and for local or spinal anaesthesia
- * omeprazole, a medicine used to treat stomach ulcers.

You may need to adjust your dose or

take an alternative medicine.

Some medicines may affect how ciprofloxacin is absorbed into the body. These include:

- * medicines containing iron, zinc, magnesium, aluminium or calcium such as antacids, multivitamins or mineral supplements
- * sucralfate, a medicine used to treat stomach ulcers
- * metoclopramide, used to treat nausea and vomiting
- * antiretroviral medicines such as didanosine, used to treat HIV infections
- * medicines such as sevelamer, used to treat high blood levels of phosphate

You may need to take it at a different time, or take an alternative medicine.

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 ciprofloxacin.

How to take this medicine

Follow all directions from 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 many tablets you will need to take. This depends 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.

Avoid taking this medication at the same time as milk, yoghurt or other products that are high in calcium. These products will interfere with the absorption of ciprofloxacin from the stomach.

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 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 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) 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 Ciprofloxacin

Things you must do

Tell your doctor immediately if you become pregnant.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you are about to have any blood tests, tell your doctor 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.

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.

If you get severe diarrhoea tell your doctor or pharmacist immediately. Do this even if it occurs several weeks after ciprofloxacin has been stopped.

Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care.

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

If you have pain or tenderness in your tendons, or have problems moving, take care to rest and not do any exercise which may strain the tendon further.

If you get a sore white mouth or tongue while taking or soon after stopping ciprofloxacin, 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 your doctor if your infection is not clearing up, or is getting worse.

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.

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.

Side effects of ciprofloxacin

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 ciprofloxacin.

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:

- * nausea, vomiting, mild diarrhoea
- * loss of appetite
- * heartburn, mild stomach pain or wind
- * agitation, anxiety or restlessness
- * problems sleeping
- * headache
- * dizziness, giddiness or light-headedness
- * tremor, twitching or weakness
- * numbness, tingling or pins and needles
- * purple or red spots on the skin
- * strange taste, smell or touch sensations.

The above list includes the more common side effects. Mostly, these are mild.

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

- * vaginal itching or discharge
- * a sore white mouth or tongue
- * mild fever
- * altered vision
- * migraine
- * difficulty walking, uncoordinated, shaking
- * excessive sweating
- * getting sunburnt very easily.
- * joint or muscle pain, muscle cramps, or inflamed, painful or ruptured tendons such as the Achilles tendon
- * bleeding or bruising more easily than normal, nose bleeds
- * frequent infections such as fever, severe chills, sore throat or mouth ulcers
- * 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
- * allergic reaction- e.g. rash, itching or hives on the skin.

These may be serious side effects. You may need medical attention. Most of these side effects are rare.

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:

- * 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
- * palpitations, or fast or irregular heart beats
- * chest pain
- * fainting
- * swelling of the face, lips, mouth or throat
- * dark, bloody or cloudy urine
- * yellowing of the skin or eyes (jaundice)
- * fits (convulsions or seizures)
- * psychotic reaction (acting strangely)
- * wheezing or difficulty breathing.

These are very serious side effects. You may need urgent medical attention or hospitalisation. Mostly, these side effects are very rare.

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 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.

After taking this medicine

Storage

Keep ciprofloxacin tablets in their original packaging until it is time to take them.

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 25 degrees 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 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.

Product description

What GenRx Ciprofloxacin looks like

- * 250 mg - white to off-white, round, film-coated tablets marked with "250" on one side and plain on the other.
- * 500 mg - white to off-white, caplet (oval) shaped, film-coated tablets marked with "500" on one side and plain on the other.
- * 750 mg - white to off-white, caplet (oval) shaped, film-coated tablets marked with "750" on one side and plain on the other.

Ingredients

Active Ingredient:

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.

GenRx Ciprofloxacin does not contain any gluten, lactose, sucrose, tartrazine or any other azo dyes.

Australian Registration Numbers

GenRx Ciprofloxacin 250mg Tablets

Blister packs of 14 tablets
AUST R Number 135911.

GenRx Ciprofloxacin 500mg Tablets

Blister packs of 14 tablets
AUST R Number 135912.

GenRx Ciprofloxacin 750mg Tablets

Blister packs of 14 tablets
AUST R Number 135913.

Sponsor

Apotex Pty Ltd
ABN 52 096 916 418
66 Waterloo Road
North Ryde NSW 2113
Australia

GenRx is a registered trade mark of Apotex Pty Ltd.

This leaflet was prepared in:
November 2008.