

# Profloxin®

*ciprofloxacin hydrochloride tablets*

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about Profloxin.

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 this medicine against the benefits they expect it will have for you.

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

**Keep this leaflet with the medicine.** You may need to read it again.

### What Profloxin is used for

This medicine is used to treat infections of the lungs, skin, bones and joints, kidney and bladder, prostate and bowel.

It contains the active ingredient ciprofloxacin hydrochloride.

Ciprofloxacin hydrochloride belongs to a group of medicines called quinolone antibiotics.

It works by killing the bacteria that are causing your 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 not addictive.

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

### Before you take Profloxin

*When you must not take it*

**Do not take this medicine if you have an allergy to:**

- **ciprofloxacin hydrochloride, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product Description**
- **any other similar medicines such as quinolone antibiotics including nalidixic acid.**

Some of the 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**
- **rash, itching or hives on the skin.**

**Do not take this medicine if you are also taking a medicine called tizanidine (Zanaflex®), used as a muscle relaxant.**

**Do not breastfeed if you are taking this medicine.**

The active ingredient in Profloxin passes into breast milk and there is a possibility that your baby may be affected.

**Do not give this medicine to children and growing adolescents unless you are told by your doctor to do so.**

Safety and effectiveness in children and growing adolescents have not been established.

**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.

**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 have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor if you have or have had any of the following medical conditions:**

- **any type of allergic reaction to ciprofloxacin or quinolone antibiotics**
- **you suffer from fits (seizures, convulsions)**
- **have had a stroke**
- **kidney disease**
- **myasthenia gravis (a condition where your muscles become weak and tire easily)**
- **a history of tendon problems associated with quinolone antibiotics**
- **any other medical problems.**

**Tell your doctor if you have previously taken corticosteroids.**

You may be at increased risk of swelling of the tendons. Symptoms include pain, tenderness and sometimes restricted movement.

**Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.**

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

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

*Taking other medicines*

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

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

- **theophylline, a medicine used to treat asthma**
- **anticoagulants, medicines used to stop blood clots such as warfarin**
- **probenecid, a medicine used to treat gout**
- **glibenclamide, a medicine used to treat diabetes**
- **cyclosporin, a medicine used in organ transplantation**
- **methotrexate, a medicine used in cancer and to treat arthritis**
- **NSAIDs (non-steroidal anti-inflammatory drugs), medicines used to treat pain, swelling and arthritis**
- **ropinirole, a medicine used to treat Parkinson's disease and restless legs syndrome**
- **lidocaine, an anaesthetic**
- **multivitamins, mineral supplements and other medicines containing iron, zinc, magnesium, aluminium or calcium**

- **sucralfate, a medicine used to treat duodenal or stomach ulcers**
- **omeprazole, a medicine used to treat ulcers and other conditions where the stomach produces too much acid**
- **metoclopramide, a medicine used to relieve nausea, vomiting and stomach pain**
- **some antiviral medicines used to treat HIV infection, such as didanosine**
- **sevelamer, a medicine used to treat high blood levels of phosphorus in patients with kidney disease who are on dialysis**
- **duloxetine, a medicine used to treat depression**
- **clozapine, a medicine used to treat schizophrenia.**

These medicines may be affected by Profloxin 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 have more information on medicines to be careful with or avoid while taking this medicine.

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## How to take Profloxin

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

They may differ from the information contained in this leaflet.

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

### *How much to take*

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 of time for some types of infections.

Your doctor may have prescribed a different dose.

**Ask your doctor or pharmacist if you are unsure of the correct dose for you.**

They will tell you exactly how much to take.

**Follow the instructions they give you.**

If you take the wrong dose, Profloxin may not work as well and your problem may not improve.

### *How to take it*

Swallow the tablets whole with a full glass of water.

### *When to take Profloxin*

**Take your medicine at about the same time each day.**

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

**Take your medicine preferably on an empty stomach, for example, 1 hour before food or 2 hours after food.**

Food can interfere with the absorption of this medicine. However, they can be taken with or without food.

**If you need to take an antacid, multivitamins, mineral supplements and other medicines containing iron, zinc, magnesium, aluminium or calcium, take it at least 2 hours before or 2 hours after your dose of Profloxin.**

Your doctor and pharmacist will have more information on medicines to avoid while taking this medicine.

### *How long to take Profloxin*

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

### *If you forget to take it*

Take your dose as soon as you remember, and continue to take it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

**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 (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Profloxin. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

Symptoms of an overdose may include drowsiness, nausea, vomiting or little or no urine.

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## While you are taking Profloxin

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*Things you must do*

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Profloxin.**

**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 develop diarrhoea, tell your doctor or pharmacist immediately.**

Do this even if it occurs several weeks after you have stopped taking this medicine. Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care.

**Do not take any medications for diarrhoea without checking with your doctor.**

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

**Drink plenty of water while you are taking Profloxin.**

This helps to stop crystals forming in the urine.

**If you get a sore white mouth or tongue while taking, or soon after stopping this medicine, tell your doctor or pharmacist. Also tell your doctor if you get vaginal itching or discharge.**

This may mean that you have a fungal infection called thrush. Sometimes the use of antibiotics allows fungi to grow. Profloxin does not work against fungi.

*Things you must not do*

**Do not take Profloxin to treat any other complaints unless your doctor tells you to.**

**Do not give your medicine to anyone else, even if they have the same condition as you.**

**Do not stop taking your medicine or lower the dosage without checking with your doctor.**

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

*Things to be careful of*

**Avoid excessive exposure to direct sunlight. Your skin may become more prone to sunburn.**

**Be careful driving or operating machinery until you know how Profloxin affects you.**

This medicine may cause dizziness and light-headedness in some people. If you have any of these symptoms, do not drive, 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 and light-headedness may be worse.

**Profloxin may increase the stimulatory effects of caffeine.**

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## Side effects

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

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

**Do not be alarmed by the following lists of side effects.**

You may not experience any of them.

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

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

- headache
- dizziness or light-headedness
- mild stomach upsets such as stomach pains, flatulence or diarrhoea
- loss of appetite or altered taste
- heartburn (dyspepsia)
- feeling sick (nausea) or vomiting
- discharge and itching in the vagina
- irritability, agitation or confusion
- difficulty sleeping.

These are the more common side effects of the medicine, and are usually mild and short-lived.

**Tell your doctor immediately if you notice any of the following:**

- **pain, inflammation or rupture of the Achilles tendon (which extends from the calf to the heel of the foot) or other tendons**
- **increased sensitivity of the skin to sunlight, resulting in getting sunburnt more easily than usual**
- **joint/muscle pain or cramping**
- **symptoms of low blood sugar (hypoglycaemia), which may include sweating, weakness, dizziness, trembling and a fast pounding heartbeat.**

The above list includes serious side effects that may require medical attention. If you experience any of the above side effects, Profloxin may need to be stopped. Serious side effects are rare.

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

- **swelling of the face, lips, mouth or throat**
- **fainting**
- **wheezing or difficulty breathing**
- **severe skin rashes, hives, itching or blistering or peeling of the skin**
- **severe abdominal or stomach cramps**
- **severe, watery or bloody diarrhoea, even if it occurs several weeks after stopping this medicine**
- **fits (seizures or convulsions)**
- **hallucinations, self-endangering behaviour**
- **yellowing of the skin and/or eyes, also called jaundice**
- **heart beating faster than normal**
- **visual disturbances**
- **ringing in the ear, loss of hearing**
- **passing little or no urine**

- **dark coloured urine.**

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

Rarely, there can be a worsening of the symptoms of myasthenia gravis. This is a condition in which the muscles become weak and tire easily, causing drooping eyelids, double vision, difficulty speaking and swallowing, and/or muscle weakness in the arms or legs.

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

Other side effects not listed above may also occur in some people.

Some of these side effects (for example kidney, liver or blood problems) can only be found when your doctor does tests from time to time to check your progress.

### *After taking Profloxin*

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

- **severe abdominal or stomach 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. Therefore, you may need urgent medical attention.

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

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## After taking Profloxin

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### *Storage*

**Keep your medicine in the original container.**

If you take it out of its original container it may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 25°C.

**Do not store Profloxin 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 tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

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## Product description

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### *What it looks like*

Profloxin comes in three types of tablets:

Profloxin 250mg - white, round, film-coated tablets with a breaking notch on one side, embossed with 'cip 250'.

Profloxin 500mg - white, oblong, film-coated tablets with a breaking notch on both sides, embossed with 'cip 500'.

Profloxin 750mg - white, oblong, film-coated tablets with a breaking notch on both sides, embossed with 'cip 750'.

Available in blisters of 14 tablets.

## *Ingredients*

Active ingredients:

- Profloxin 250mg - 250mg  
ciprofloxacin (as ciprofloxacin hydrochloride)
- Profloxin 500mg - 500mg  
ciprofloxacin (as ciprofloxacin hydrochloride)
- Profloxin 750mg - 750mg  
ciprofloxacin (as ciprofloxacin hydrochloride).

Inactive ingredients:

- colloidal anhydrous silica
- povidone
- magnesium stearate
- microcrystalline cellulose
- stearic acid
- sodium starch glycollate type A
- croscarmellose sodium
- hypromellose
- macrogol 6000
- talc
- titanium dioxide.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

## *Supplier*

Profloxin is supplied in Australia by:

**Sandoz Pty Ltd**

ABN 60 075 449 553

Level 4, 100 Harris St

Pymont NSW 2009

Tel: 1800 634 500

This leaflet was revised in March 2009.

### **Australian Register Numbers**

250mg film-coated tablets: AUST R 81460 (blisters)

500mg film-coated tablets: AUST R 81461 (blisters)

750mg film-coated tablets: AUST R 81462 (blisters)