

# AURO-CIPROFLOXACIN 250, 500 & 750

*Ciprofloxacin (as hydrochloride)*

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about AURO-CIPROFLOXACIN tablets. 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 AURO-CIPROFLOXACIN tablets 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 AURO-CIPROFLOXACIN is used for

AURO-CIPROFLOXACIN tablets are used for the treatment of infections of the lungs, skin, bones, joints, kidneys, bladder, prostate and bowel. AURO-CIPROFLOXACIN is also used to treat inhalational anthrax (an infection caused by breathing in the spores of bacteria).

AURO-CIPROFLOXACIN tablets contain the active ingredient, ciprofloxacin, which is an antibiotic belonging to a group of medicines called quinolones (pronounced kwin-o-lones). These antibiotics work by killing the bacteria that are causing your infection.

AURO-CIPROFLOXACIN will not work against infections caused by viruses such as colds or the flu.

**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.

### Before you take AURO-CIPROFLOXACIN

#### *When you must not take it*

**Do not take AURO-CIPROFLOXACIN if you have an allergy to:**

- ciprofloxacin, the active ingredient in AURO-CIPROFLOXACIN
- any of the ingredients listed at the end of this leaflet
- other medicines belonging to the quinolone chemical family (e.g. moxifloxacin, norfloxacin, 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 AURO-CIPROFLOXACIN if you are also taking a medicine called tizanidine, a muscle relaxant used to treat spasticity associated with multiple sclerosis, injury or diseases of the spinal cord.**

AURO-CIPROFLOXACIN can interfere with tizanidine and can lead to undesirable side effects.

**Do not take this medicine after the expiry date printed on the pack and blister.**

If it has expired return it to your pharmacist for disposal.

**Do not take this medicine if the packaging is torn or shows signs of tampering.**

If the packaging 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 are pregnant or plan to become pregnant.**

AURO-CIPROFLOXACIN is not recommended if you are pregnant but your doctor will assess the benefit if required. Medicines similar to AURO-CIPROFLOXACIN have caused joint disease in immature animals.

**Tell your doctor if you are breastfeeding.**

AURO-CIPROFLOXACIN is excreted into the breast milk. Your doctor will tell you whether you should take it and temporarily stop breastfeeding while you are taking the tablets.

**AURO-CIPROFLOXACIN is not recommended in children under 18 years of age except for use in inhalational anthrax.**

**AURO-CIPROFLOXACIN should be used with caution in elderly patients as they are more prone to side effects.**

**Tell your doctor if you:**

- suffer from epilepsy (seizures, convulsions), have had a stroke, or have kidney or liver disease
- have arrhythmias (fast or irregular heartbeats). AURO-CIPROFLOXACIN may increase the risk of arrhythmias, especially in the elderly or patients with low potassium levels
- have previously taken corticosteroids. You may be at increased risk of swelling of the tendons. Symptoms include pain, tenderness and sometimes restricted movement
- have myasthenia gravis, a condition where the muscles become weak. AURO-CIPROFLOXACIN can worsen the symptoms of this condition
- have a history of tendon disorders with the use of quinolones (e.g. moxifloxacin, norfloxacin, nalidixic acid)

**If you have not told your doctor or pharmacist about any of the above, tell them before you start taking AURO-CIPROFLOXACIN.**

*Taking other medicines*

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

Some medicines may be affected by AURO-CIPROFLOXACIN. These medicines include:

- medicines used to treat arrhythmias (fast or irregular heartbeats)
- theophylline, a medicine used to treat asthma
- oral anticoagulants, warfarin and its metabolites, medicines used to stop blood clots
- glibenclamide, a medicine used to treat diabetes

- didanosine, a medicine used to treat viral infections
- cyclosporin, a medicine used to suppress the immune system
- non-steroidal anti-inflammatory drugs (NSAIDs), medicines used to treat pain, arthritis and other inflammatory conditions
- methotrexate, a medicine used to treat certain types of cancers, severe psoriasis or severe rheumatoid arthritis
- duloxetine, a medicine used to treat depression and stress urinary incontinence
- clozapine, a medicine used to treat schizophrenia
- ropinirole, a medicine used to treat Parkinson's disease or restless legs syndrome
- the local anaesthetic lidocaine, a medicine used to numb pain or cause loss of sensation
- sildenafil, a medicine used to treat erectile dysfunction

These medicines may be affected by AURO-CIPROFLOXACIN, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Some medicines may interfere with the absorption of AURO-CIPROFLOXACIN. These include:

- multivitamins, mineral supplements, antacids (used for indigestion) and other medicines containing iron, zinc, magnesium, aluminium or calcium
- sucralfate, a medicine used to treat duodenal or stomach ulcers
- medicines used to treat HIV infection
- probenecid, a medicine used to treat gout
- omeprazole, a medicine used to treat stomach ulcers and other conditions where stomach produces too much acid
- sevelamer, a medicine used to treat high blood levels of phosphorus in patients with kidney disease who are on dialysis
- metoclopramide, a medicine used to relieve nausea and vomiting, heartburn, and stomach pain

You can still take these medicines while you are taking AURO-CIPROFLOXACIN. However, you must take AURO-CIPROFLOXACIN at least 2 hours before or 2 hours after taking any of these medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

### How to take AURO-CIPROFLOXACIN

**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 printed on the pharmacist label, ask your doctor or pharmacist for help.**

*How much to take*

Your doctor or pharmacist will tell you how much and how often you should take AURO-CIPROFLOXACIN. This will depend on the type of infection and any medical conditions you may have.

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 types of infection. The dose will be determined by your doctor as it depends upon the type of infection you have.

#### *When to take it*

AURO-CIPROFLOXACIN tablets are usually taken twice a day. Take your tablets at the same time each day preferably on an empty stomach. However, they can be taken with or without food.

#### *How long to take it*

The length of treatment may vary from one to 28 days or longer depending on the type of infection. **Continue taking AURO-CIPROFLOXACIN until you have finished the blister 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.

#### *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 it as you would normally.

Do not take a double dose to make up for the dose that you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when 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 in Australia 13 11 26, in New Zealand 0800 POISON or 0800 764 766), or go to the Accident and Emergency department at your nearest hospital, if you think you or anyone else may have taken too much AURO-CIPROFLOXACIN. Do this even if there are no signs of discomfort or poisoning.** You may need urgent medical attention.

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#### While you are taking AURO-CIPROFLOXACIN

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##### *Things you must do*

**Tell all the doctors, dentists and pharmacists who are treating you that you are taking AURO-CIPROFLOXACIN.**

**Tell your doctor if you need to have a surgical or dental procedure that you are taking AURO-CIPROFLOXACIN.**

**AURO-CIPROFLOXACIN may affect the results of certain laboratory tests.**

If you are about to have any tests, tell your doctor that you are taking this medicine.

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

Drink plenty of water while you are taking AURO-CIPROFLOXACIN. This helps to stop crystals forming in the urine.

**If you become pregnant while you are taking AURO-CIPROFLOXACIN, tell your doctor immediately.**

#### **If you develop diarrhoea, tell your doctor or pharmacist immediately**

- even if it occurs several weeks after you have stopped taking AURO-CIPROFLOXACIN. 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 or pharmacist.

#### **Tell your doctor immediately if you experience symptoms of depression or self-endangering behaviour.**

AURO-CIPROFLOXACIN should be discontinued immediately.

#### *Things you must not do*

**Do not give your AURO-CIPROFLOXACIN tablets to anyone else, even if they have the same condition as you.**

Do not use AURO-CIPROFLOXACIN to treat other conditions unless your doctor tells you to.

**Do not stop taking your tablets because you are feeling better, unless your doctor told you to do so.**

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

#### *What to be careful of*

##### **Avoid excessive exposure to direct sunlight.**

Your skin may become more prone to sunburn. If such a reaction occurs, stop taking AURO-CIPROFLOXACIN immediately and tell your doctor.

##### **Be careful driving or operating machinery until you know how AURO-CIPROFLOXACIN affects you.**

AURO-CIPROFLOXACIN tablets may cause dizziness in some patients, especially after the first few doses. Your ability to drive and/or operate machinery may be impaired.

If you drink alcohol while taking this medicine, dizziness may be worse.

AURO-CIPROFLOXACIN tablets 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 AURO-CIPROFLOXACIN.**

All medicines have side effects. Sometimes they are serious, most of the time they are not. In serious cases, you may need medical attention.

**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 if you notice any of the following and they worry you:**

- nausea
- diarrhoea

These are the common side effects of AURO-CIPROFLOXACIN. They are usually mild and short-lived.

**Tell your doctor immediately, or go to the Accident and Emergency department at your nearest hospital if you notice any of the following:**

- severe skin rashes, peeling of the skin and/or mucosal reactions

- signs of allergy such as rash, swelling of the face, lips, mouth, throat or other parts of the body, shortness of breath, wheezing or trouble breathing
- fainting
- yellowing of the skin and eyes, also called jaundice
- severe watery or bloody diarrhoea, even if it occurs several weeks after taking your tablets
- fits (seizures, convulsions)
- confusion, nightmares, hallucinations, and psychotic reaction (even progressing to self-endangering behaviour)
- fast or irregular heart beats
- visual disturbances
- ringing in the ear, loss of hearing
- abdominal pain/cramps. Very rarely this can progress to a serious condition accompanied by fever and fatigue.

These serious side effects are rare. If you have them, you may need urgent medical attention.

Photosensitivity (getting sunburnt very easily) can occasionally occur with AURO-CIPROFLOXACIN. However, it is temporary and staying out of direct sunlight while on AURO-CIPROFLOXACIN tablets will prevent it from happening.

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 in speaking and swallowing, and sometimes muscle weakness in the arms or legs.

Rarely, the Achilles tendon (extending from the calf to the heel of the foot) or other tendons have been torn after AURO-CIPROFLOXACIN therapy. Tell your doctor immediately if you feel any discomfort, pain or inflammation of a tendon.

Rarely, you may experience hyperglycaemia (high blood sugar). Symptoms include increased thirst, appetite and urination. Tell your doctor if you experience these symptoms.

**If you experience any of these symptoms during treatment with AURO-CIPROFLOXACIN tablets, tell your doctor or pharmacist immediately. AURO-CIPROFLOXACIN may need to be discontinued.**

**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 patients.

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#### After using AURO-CIPROFLOXACIN

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##### *Storage*

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

If you take the tablets out of the box or the blister pack they may not keep well.

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

**Do not store AURO-CIPROFLOXACIN or any other medicine in the bathroom, near a sink, or on a window sill.**

**Do not leave it in the car.**

Heat and damp can destroy some medicines.

**Keep your tablets where children cannot reach them.**

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 AURO-CIPROFLOXACIN tablets or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

**Return any unused medicine to your pharmacist.**

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### Product Description

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#### *What it looks like*

AURO-CIPROFLOXACIN 250, 500 & 750 is presented in pack size of 14, 28 & 60 tablets in blister.

- **AURO-CIPROFLOXACIN 250 (AUST R 175437)**  
White to off-white, round shaped, film coated tablets, with a score line on one side and debossed with 'F' and '23' with a score line in between on the other side.
- **AURO-CIPROFLOXACIN 500 (AUST R 175440)**  
White to off-white, capsule shaped, film coated tablets, with a score line on one side and debossed with 'F 22' on the other side.
- **AURO-CIPROFLOXACIN 750 (AUST R 175439)**  
White to off-white, capsule shaped, film coated tablets debossed with 'C' on one side and '93' on the other side.

#### *Ingredients*

##### **Active Ingredient:**

Ciprofloxacin (as hydrochloride)

Each tablet contains either 250, 500 & 750 mg of ciprofloxacin as hydrochloride.

##### **Other Ingredients:**

- microcrystalline cellulose
- sodium starch glycollate type A
- povidone
- colloidal anhydrous silica
- magnesium stearate
- hypromellose
- macrogol 400
- titanium dioxide

#### *Name and Address of the Sponsor*

##### **Aurobindo Pharma Australia Pty Ltd**

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##### **Date of Approval**

9 December 2011