APO-CIPROFLOXACIN

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using APO-CIPROFLOXACIN?

APO-CIPROFLOXACIN contains the active ingredient ciprofloxacin (as hydrochloride). APO-CIPROFLOXACIN is used to treat certain infections of the lungs, skin, bones and joints, kidney and bladder, prostate and bowel.

For more information, see Section 1. Why am I using APO-CIPROFLOXACIN? in the full CMI.

2. What should I know before I use APO-CIPROFLOXACIN?

Do not take if you have ever had an allergic reaction to ciprofloxacin, other quinolone antibiotics including nalidixic acid, moxifloxacin, norfloxacin, or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use APO-CIPROFLOXACIN? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with APO-CIPROFLOXACIN and affect how it works. A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use APO-CIPROFLOXACIN?

Your doctor will tell you how much and how often you should take APO-CIPROFLOXACIN. This will depend on the type of infection and any medical conditions you have. More instructions can be found in Section 4. How do I use APO-CIPROFLOXACIN? in the full CMI.

5. What should I know while using APO-CIPROFLOXACIN?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are taking APO-CIPROFLOXACIN. • If you develop diarrhoea, tell your doctor or pharmacist immediately. Do this even if it occurs several weeks after you have stopped taking APO-CIPROFLOXACIN. • Tell your doctor immediately if you experience symptoms of depression or self-endangering behaviour. • Tell your doctor immediately if you develop pain, burning, tingling, numbness or weakness is any part of the body.
Things you should not do	• Do not take APO-CIPROFLOXACIN to treat any other complaints 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.
Driving or using machines	• Be careful driving or operating machinery until you know how APO-CIPROFLOXACIN affects you. APO-CIPROFLOXACIN may cause dizziness in some people, especially after the first few doses.
Drinking alcohol	• If you drink alcohol while taking this medicine, dizziness may be worse.
Looking after your medicine	• Store APO-CIPROFLOXACIN in a cool dry place below 25°C. • Keep your tablets in the pack until it is time to take them.

For more information, see Section 5. What should I know while using APO-CIPROFLOXACIN? in the full CMI.

6. Are there any side effects?

Less serious side effects: nausea or vomiting, diarrhoea. **Serious side effects:** severe skin rashes, peeling of the skin, yellowing of the skin and eyes also called jaundice, severe watery or bloody diarrhoea, nightmares, hallucinations and psychotic reaction, fast or irregular heartbeats, visual disturbances, abdominal pain/cramps, pain, burning, tingling, numbness and/or weakness in your limbs. **This is not a complete list of all possible side effects**

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

WARNING: Serious disabling and potentially irreversible.

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.

APO-CIPROFLOXACIN Tablets

Active ingredient(s): *Ciprofloxacin (as hydrochloride)*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking APO-CIPROFLOXACIN. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking APO-CIPROFLOXACIN.**

Where to find information in this leaflet:

1. Why am I using APO-CIPROFLOXACIN?
2. What should I know before I use APO-CIPROFLOXACIN?
3. What if I am taking other medicines?
4. How do I use APO-CIPROFLOXACIN?
5. What should I know while using APO-CIPROFLOXACIN?
6. Are there any side effects?
7. Product details

1. Why am I using APO-CIPROFLOXACIN?

APO-CIPROFLOXACIN contains the active ingredient ciprofloxacin (as hydrochloride). APO-CIPROFLOXACIN is an antibiotic belonging to the group of medicines called quinolones (pronounced kwin-olones). These antibiotics work by killing the bacteria causing your infection.

APO-CIPROFLOXACIN does not work against infections caused by viruses, such as colds or flu.

APO-CIPROFLOXACIN is used to treat certain infections of the:

- lungs
- skin
- bones and joints
- kidney and bladder
- prostate
- bowel.

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.What should I know before I use APO-CIPROFLOXACIN?

Warnings

Do not use APO-CIPROFLOXACIN if:

- you are allergic to ciprofloxacin, other quinolone antibiotics including nalidixic acid, moxifloxacin, norfloxacin, or any of the ingredients listed at the end of this leaflet.

  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.

  Always check the ingredients to make sure you can take this medicine.
- 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.

  APO-CIPROFLOXACIN can interfere with tizanidine and can lead to undesirable side effects.
- the expiry date printed on the pack has passed or if the packaging is torn or shows signs of tampering. If you are not sure whether you should start taking this medicine, talk to your doctor.

If you are not sure whether you should be taking APO-CIPROFLOXACIN, talk to your doctor.

Check with your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes.
- have or have had any of the following medical conditions:
  - epilepsy, fits, seizures or convulsions
  - stroke
  - kidney disease
  - liver disease
  - arrhythmias (fast or irregular heartbeats). APO-CIPROFLOXACIN may increase the risk of arrhythmias, especially in the elderly or patients with low potassium levels
  - conditions where you have taken corticosteroids. You may be at increased risk of swelling of the tendons. Symptoms include pain, tenderness and sometimes restricted movement
  - myasthenia gravis, a condition where the muscles become weak. APO-CIPROFLOXACIN can worsen symptoms of this condition
  - a history of tendon disorders with the use of quinolones (e.g. moxifloxacin, norfloxacin, nalidixic acid)
  - have or have had a mental illness

- have diabetes.
- Arteriosclerosis which is a thickening of the artery walls or cerebral arteriosclerosis
- Glucose-6-phosphate dehydrogenase deficiency

- Take any medicines for any other condition.
- are pregnant or plan to become pregnant or breastfeeding

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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

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

APO-CIPROFLOXACIN is not recommended if you are pregnant. Medicines similar to APO-CIPROFLOXACIN have caused joint disease in immature animals. Your doctor will discuss the risks and benefits of taking APO-CIPROFLOXACIN during pregnancy.

Do not breast-feed if you are taking this medicine.

Tell your doctor if you are breastfeeding or plan to breastfeed. APO-CIPROFLOXACIN passes into breast milk and may affect your baby. Your doctor will tell you whether you should take APO-CIPROFLOXACIN or temporarily stop breastfeeding while you are taking the tablets.

Use in children

APO-CIPROFLOXACIN is not recommended for children under 18 years of age.

Use in elderly

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

Epidemiologic studies report an increase risk of aortic aneurysms and dissection, particularly in elderly patients.

2. What if I am taking other medicines?

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

Some medicines may be affected by APO-CIPROFLOXACIN or may affect how well it works. These include:

- medicines used to treat arrhythmias (fast or irregular heartbeats)
- theophylline, a medicine used to treat asthma
- oral anticoagulants, medicines used to prevent blood clots such as warfarin and its derivatives
- phenytoin, a medicine used to treat epilepsy
- medicines used to control diabetes
- didanosine, a medicine used to treat viral infections
- ciclosporin, a medicine used to suppress the immune system following organ transplantation
- NSAIDs (non-steroidal anti-inflammatory drugs), medicines used to treat pain, arthritis and other inflammatory conditions
- methotrexate, a medicine used to treat severe rheumatoid arthritis, severe psoriasis or some types of cancer
- duloxetine, a medicine used to treat depression, anxiety and nerve pain in people with diabetes
- clozapine, a medicine used to treat schizophrenia ropinirole, a medicine used to treat Parkinson's disease or restless legs syndrome
- lidocaine, a local anaesthetic medicine used to numb pain or cause loss of sensation
- pentoxifylline, a medicine used to treat circulation disorders
- sildenafil, a medicine used to treat erectile dysfunction
- agomelatine, a medicine used to treat depression
- zolpidem, a medicine used to treat sleep disorders.
- levothyroxine, a medicine used to treat hypothyroidism
- Fluoroquinolones, an antibiotic medicine used to treat bacterial infections.

These medicines may be affected by APO-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 that may interfere with the absorption of APO-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 the 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 treat nausea and vomiting, heartburn and stomach pain.

You can still take these medicines while you are taking APO-CIPROFLOXACIN. However, you must take APO-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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect APO-CIPROFLOXACIN.

3. How do I use APO-CIPROFLOXACIN?

Take Ciprofloxacin tablets exactly as your doctor has prescribed.

Follow all directions given to you by your doctor or pharmacist. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how much and how often you should take APO-CIPROFLOXACIN. This will depend on the type of infection and any medical conditions you 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 of time for some types of infection.

Elderly people and people with kidney problems may need smaller doses.

When to take APO-CIPROFLOXACIN

APO-CIPROFLOXACIN tablets are usually taken twice a day.

Take your tablets at the same time each day, preferably on an empty stomach. However, APO-CIPROFLOXACIN can be taken with or without food.

How to take APO-CIPROFLOXACIN?

- Swallow the tablet whole with a full glass of water.

How long to take APO-CIPROFLOXACIN for

- Continue taking your medicine for as long as your doctor tells you.
- The length of treatment may vary from 1 to 28 days or longer depending on the type of infection.
- Do not stop taking APO-CIPROFLOXACIN even if you are feeling better, unless advised by your doctor.
- If you stop taking your medicine too soon, the infection may not clear completely or your symptoms may return.

If you forget to use APO-CIPROFLOXACIN

If you forget to take APO-CIPROFLOXACIN tablets and it is:

- 6 hours or more until your next scheduled dose, take your missed dose right away. Then take the next dose at your regular time.
- Less than 6 hours until your next scheduled dose, do not take the missed dose. Take the next dose at your regular time. Do not take a double dose to make up for the dose you missed.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you use too much APO-CIPROFLOXACIN

If you think that you have used too much APO-CIPROFLOXACIN, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

4. What should I know while using APO-CIPROFLOXACIN?

Things you should do

- Tell any other doctors, dentists and pharmacists who are treating you that you are taking APO-CIPROFLOXACIN.
- If you are about to start any new medicine, tell your doctor or pharmacist that you are taking APO-CIPROFLOXACIN.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are taking APO-CIPROFLOXACIN.
- If you are about to have any laboratory, blood or urine tests, tell your doctor that you are taking APO-CIPROFLOXACIN.
- It may affect the results of some tests.
- Drink plenty of water while you're taking APO-CIPROFLOXACIN. This helps to stop crystals forming in your urine.

Call your doctor straight away if you:

- become pregnant while taking APO-CIPROFLOXACIN.
- develop diarrhoea. Do this even if it occurs several weeks after you have stopped taking APO-CIPROFLOXACIN.
  Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care.
  Do not take any medicines for diarrhoea without checking with your doctor or pharmacist.
- experience symptoms of depression or selfendangering behaviour. APO-CIPROFLOXACIN should be discontinued immediately.
- develop pain, burning, tingling, numbness or weakness is any part of the body. APO-CIPROFLOXACIN should be discontinued immediately.

Things you should not do

- Do not take APO-CIPROFLOXACIN 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 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.

Things 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 APO-CIPROFLOXACIN immediately and tell your doctor.
- APO-CIPROFLOXACIN tablets may increase the stimulatory effects of caffeine.

Driving or using machines

Be careful driving or operating machinery until you know how APO-CIPROFLOXACIN affects you.

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

Drinking alcohol

Tell your doctor if you drink alcohol.

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

Looking after your medicine

- Keep APO-CIPROFLOXACIN tablets in the original pack until it is time to take them.
- Keep APO-CIPROFLOXACIN tablets in a cool dry place where the temperature is below 25°C.

Do not store APO-CIPROFLOXACIN, or any other medicine, in the bathroom or near a sink.

Do not leave medicines in the car or on window sills. Heat and dampness can destroy some medicines.

Keep your medicines where children cannot reach them. A locked cupboard at least one-and-a-half metres (1.5 m) above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

5. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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

Less serious side effects

Less serious side effects	What to do
• nausea or vomiting • diarrhoea. • Decreased appetite	**Speak to your doctor if you have any of these less serious side effects. These are the more mild and common side effects.**

Serious side effects

Serious side effects	What to do
• 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, mania and psychotic reaction (even progressing to self-endangering behaviour) • Occurrence of pustules or blisters on the skin. • fast or irregular heartbeats • visual disturbances (eyesight problems) • ringing in the ear, loss of hearing • abdominal pain/cramps. Very rarely this can progress to a serious condition accompanied by fever and fatigue • back pain, chest pain, pain in arms and legs, burning, tingling numbness and/or weakness in your limbs • hypersensitivity reaction called DRESS (Drug Reaction with Eosinophilia and Systemic Symptoms) which may include fever, extensive skin rash, swollen lymph nodes, blood abnormalities and inflammation of internal organs like liver, lung or kidney. • Fungal or Yeast infection • Increase in blood sugar levels (hyperglycaemia), decreased	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.** These may be serious side effects that may need urgent medical attention

blood sugar levels (hypoglycaemia)	

In isolated instance, some serious side effects may be longlasting (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.

Photosensitivity (getting sunburnt very easily) can occasionally occur with APO-CIPROFLOXACIN. However, it is temporary and staying out of direct sunlight while taking APO-CIPROFLOXACIN will prevent this 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 muscle in the leg to the heel of the foot) or other tendons have been torn after APO-CIPROFLOXACIN therapy. This may occur even within the first 48 hours of treatment and up to several months after completing treatment with APO-CIPROFLOXACIN. This risk of tendon damage may be increased in elderly patients, during strenuous physical activity, if you are currently being treated with a type of medicine called corticosteroids, if you have reduced kidney function or have received solid organ transplants.

Tell your doctor immediately if you feel any discomfort, pain or inflammation of a tendon.

Rarely, you may experience hyperglycaemia (high blood sugar) or hypoglycaemia (low blood sugar).

Symptoms of hyperglycaemia include increased thirst, appetite and urination. Symptoms of hypoglycaemia include weakness, shaking, sweating, light headedness, headache, behavioural changes, confusion, numbness/pins and needles in the lips, fingers or toes, irritability and hunger. Tell your doctor if you experience these symptoms.

Heart valve regurgitation or “leaks” in the of the heart valve have been reported in patients treated with ciprofloxacin & fluoroquinolones.

The risk of aortic aneurysm and dissection, and their rupture may also be increase in patients treated with both ciprofloxacin & systemic corticosteroids.

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

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

6. Product details

This medicine is available with a doctor's prescription.

What APO-CIPROFLOXACIN contains

Active ingredient (main ingredient)	Ciprofloxacin hydrochloride
Other ingredients (inactive ingredients)	APO-CIPROFLOXACIN tablets contain: • maize starch • microcrystalline cellulose • crospovidone • colloidal anhydrous silica • pregelatinised maize starch • magnesium stearate • Opadry II White 85F28751 (contains colour 171).
Potential allergens	None

Do not take this medicine if you are allergic to any of these ingredients.

The tablets are gluten free.

What APO-CIPROFLOXACIN looks like

APO-CIPROFLOXACIN comes in 3 strengths of tablets:

APO-Ciprofloxacin 250, Tablets, 250 mg (White to off white, round, convex, scored film-coated tablet, debossed CR/250 on one face and plain on the other side)

AUST R 135650

APO-Ciprofloxacin 500, Tablets, 500 mg (White to off white, oblong, biconvex, scored film coated tablet, debossed CR/500 on one face and plain on the other side)

AUST R 135651

APO-Ciprofloxacin 750, Tablets, 750 mg (White to off white, oblong, biconvex, unscored film-coated tablet, debossed CR 750 on one face and plain on the other side)

AUST R 135652

Each pack contains 14 tablets.

Who distributes APO-CIPROFLOXACIN

Arrotex Pharmaceuticals Pty Ltd

15-17 Chapel St

Cremorne VIC 3121

www.arrotex.com.au

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