

CIFRAN

Ciprofloxacin hydrochloride Tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about CIFRAN.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

This leaflet was last updated on the date at the end of this leaflet. More recent information may be available. The latest Consumer Medicine Information is available from <https://www.ebs.tga.gov.au/> and may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking CIFRAN against the benefits it is expected to 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 CIFRAN is used for

CIFRAN is used to treat certain bacterial infections such as:

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

CIFRAN tablets contain the active ingredient, ciprofloxacin, which is an antibiotic belonging to a group of medicines called quinolones (pronounced KWIN-a-lones).

This medicine works by killing the bacteria which cause these infections. This helps your body to fight the infection.

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

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

Your doctor may have prescribed it for another reason.

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

There is no evidence that CIFRAN is addictive.

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

Before you take CIFRAN

When you must not take it

Do not take CIFRAN if you have an allergy to:

- ciprofloxacin, the active ingredient in CIFRAN
- any of the ingredients listed at the end of this leaflet
- any other medicines belonging to the quinolone chemical family such as moxifloxacin, norfloxacin, or 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 CIFRAN 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.

CIFRAN can interfere with tizanidine and can lead to undesirable side effects such as low blood pressure and drowsiness.

Do not take this medicine after the expiry date (EXP) 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, including aspirin or non-steroidal anti-inflammatory drugs (NSAIDs), or any other substances such as foods, preservatives or dyes.

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

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

Tell your doctor if you are breastfeeding.

CIFRAN 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.

CIFRAN 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). CIFRAN 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. CIFRAN 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 about any of the above, tell them before you start taking CIFRAN.

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 CIFRAN may interfere with each other. These include:

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

- oral antidiabetic agents
- didanosine, a medicine used to treat viral infections
- cyclosporin, a medicine used to control the body's 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, 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
- 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 CIFRAN, or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Some medicines may interfere with the absorption of CIFRAN. 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 CIFRAN.

However, you must take CIFRAN at least 2 hours before or 2 hours after taking any of these medicines to make sure it is absorbed properly.

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

How to take CIFRAN

Carefully 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 or pharmacist will tell you how much and how often you should take CIFRAN. 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 type of infections. The dose will be determined by your doctor as it depends on the type of infection you have.

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 CIFRAN from the stomach.

However, if the milk, yoghurt or other high calcium products are ingredients of a meal, they will not interfere with CIFRAN absorption.

When to take it

CIFRAN tablets are usually taken twice a day.

Take your tablets at 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.

It does not matter if you take this medicine 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 CIFRAN.

How long to take it

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

Continue taking CIFRAN 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.

Check with your doctor if you are not sure how long you should be taking it for.

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 tablets as you would normally.

Do not take a double dose to make up for the dose 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 Australia 13 11 26 or New Zealand 0800 POISON or 0800 764 766) 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 CIFRAN.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking CIFRAN

Things you must do

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

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.

CIFRAN 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 become pregnant while taking this medicine, tell your doctor immediately.

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.

CIFRAN 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 outdoors, wear protective clothing and use a 15+ sunscreen. If your skin does appear to be burning, stop taking this medicine and tell your doctor.

If you get severe diarrhoea tell your doctor or pharmacist immediately. Do this even if it occurs several weeks after CIFRAN 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 get a sore white mouth or tongue while taking or soon after stopping CIFRAN, 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. CIFRAN does not work against fungi.

Tell your doctor immediately if you experience symptoms of depression or self-endangering behaviour. CIFRAN should be discontinued immediately.

Things you must not do

Do not use CIFRAN 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 because you are feeling better, unless advised by 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

Avoid excessive exposure to direct sun.

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

Be careful driving or operating machinery, until you know how CIFRAN affects you.

This medicine may cause dizziness, light-headedness or drowsiness in some people. 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.

CIFRAN tablets may increase the stimulatory effects of caffeine.

Side Effects

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

This medicine helps most people with bacterial infections, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

If you are over 65 years of age you may have an increased chance of getting side effects.

Do not be alarmed by the following list 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:

- nausea or vomiting
- mild diarrhoea

The above list includes more common side effects of CIFRAN. They are usually mild and short-lived.

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

- 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 heartbeats
- 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 CIFRAN. However, it is temporary and staying out of direct sunlight while on CIFRAN 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 CIFRAN therapy.

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.

Contact your doctor if you experience these symptoms.

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

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

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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 CIFRAN:

- 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 CIFRAN

Storage

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

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

Keep your tablets in a cool dry place where the temperature stays below 25°C, protected from light and moisture.

Do not store CIFRAN 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-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking the tablets or the expiry date has passed, 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 CIFRAN looks like

CIFRAN tablets are available in three strengths, each in blister packs of 14 tablets:

- 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:

CIFRAN tablets contain 250 mg, 500 mg or 750 mg of the active ingredient, ciprofloxacin as ciprofloxacin hydrochloride.

Inactive ingredients:

CIFRAN also contains:

- microcrystalline cellulose
- maize starch
- magnesium stearate
- purified talc
- anhydrous colloidal silica
- sodium starch glycollate
- purified water
- hypromellose
- titanium dioxide
- macrogol 400.

Australian Register Numbers

- **CIFRAN 250 mg** tablets - AUST R 135660.
- **CIFRAN 500 mg** tablets - AUST R 135661.
- **CIFRAN 750 mg** tablets - AUST R 135662.

Sponsor

CIFRAN is supplied in Australia by:

Ranbaxy Australia Pty Ltd

9-13 Waterloo Road

Macquarie Park NSW 2113

Australia

This leaflet was prepared in December 2013.