

CIPFLOX

***Ciprofloxacin film coated tablets
250 mg, 500 mg and 750 mg***



What is in this leaflet

Please read this leaflet carefully before you start taking CIPFLOX.

This leaflet answers some common questions about CIPFLOX 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 CIPFLOX 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 CIPFLOX is used for

CIPFLOX is used to treat infections of the:

- bronchial tubes and lungs,
- skin,
- bones and joints,
- kidneys,
- bladder,
- genital organs including prostate,
- abdomen
- blood.

CIPFLOX is also used to treat inhalational anthrax (an infection caused by breathing in the spores of bacteria).

CIPFLOX tablets contain the active ingredient ciprofloxacin. It belongs

to a group of antibiotics called quinolones.

These antibiotics work by killing the bacteria that are causing your infection.

Your doctor may have prescribed it for another reason.

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

CIPFLOX is available only with a doctor's prescription.

There is no evidence that CIPFLOX is addictive.

Before you take CIPFLOX

When you must not take it

Do not take CIPFLOX if you have an allergy to:

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

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 CIPFLOX if you are taking a medicine called tizanidine, a muscle relaxant used to treat spasticity associated with multiple sclerosis, injury or diseases of

the spinal cord. CIPFLOX can interfere with tizanidine and this can lead to undesirable side effects.

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 CIPFLOX

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:

- fits, seizures or convulsions
- stroke or reduced blood flow in the brain
- liver or kidney disease or other medical problems
- if you are taking corticosteroids. You may be at increased risk of damage of the tendons. Symptoms include pain, swelling and sometimes restricted movement.
- any heart conditions such as heart attack (myocardial infarction) or heart failure
- fast, slow or irregular heartbeat (arrhythmias), or congenital long QT syndrome. CIPFLOX may increase the risk of arrhythmias.
- uncorrected electrolyte imbalances such as low potassium or magnesium levels
- myasthenia gravis, a condition where the

muscles become weak. CIPFLOX can make the symptoms of this condition worse

- tendon problems such as inflamed or ruptured tendons, especially when these occurred with the use of quinolones (such as naladixic acid, norfloxacin or moxifloxacin)
- aortic aneurysm
- Marfan syndrome, Ehlers-Danlos syndrome (disorders that affects the connective tissue)
- inflamed blood vessels
- high blood pressure
- narrow blood vessels
- diabetes. Cipflox may cause disturbances in blood sugar levels, especially in elderly patients treated with oral medicines or insulin to lower the blood sugar.

Tell your doctor if you are pregnant or plan to become pregnant. CIPFLOX is not recommended if you are pregnant as safety in pregnancy has not been established. Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you are breast feeding. The use of CIPFLOX is not recommended during breast feeding as CIPFLOX is excreted into the breast milk. Talk to you doctor about whether you should take CIPFLOX and temporarily stop breastfeeding while taking the tablets.

Do not give CIPFLOX to children under 18 years of age unless you are told to do so by a doctor.

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

Taking other medicines

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

You should also tell any health professional who is prescribing a new medication for you that you are taking CIPFLOX.

Some medicines may interfere with CIPFLOX. These include:

- corticosteroids
- anti-arrhythmic medicines used to help control heart rhythm
- tricyclic antidepressant, such as amitriptyline or nortriptyline
- antipsychotic medicines used to treat mental health disorders
- erythromycin, roxithromycin or other macrolide antibiotics used to treat infections
- multivitamins, mineral supplements and other medicines containing iron, zinc, magnesium, aluminium or calcium
- antacids, medicines used to treat indigestion, heartburn or upset stomachs
- 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
- medicines used to treat high levels of phosphates in patients with kidney diseases such as sevelamer or lanthanum carbonate
- metoclopramide, a medicine used to relieve nausea and vomiting
- didanosine, a medicine used to treat viral infections.
- probenecid, a medicine used to treat gout
- theophylline, a medicine used to treat asthma
- caffeine containing products
- pentoxifylline, a medicine used to treat muscle pain
- phenytoin, a medicine used to control seizures (epilepsy)
- NSAIDs, medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis
- cyclosporin, an immunosuppressant medicine used to help prevent organ transplant rejection
- medicines used to stop blood clots such as warfarin, acenocoumarol, phenprocoumon or fluindione
- methotrexate, a medicine used to treat certain types of cancers, severe psoriasis and severe rheumatoid arthritis

- duloxetine, a medicine used to treat depression, anxiety and stress urinary incontinence
- ropinirole, a medicine used to treat Parkinson's Disease
- lidocaine, a local anaesthetic and medicine used to treat arrhythmias
- clozapine, a medicine used to treat schizophrenia
- sildenafil, a medicine used to treat erectile dysfunction
- agomelatine, a medicine used to treat depression
- zolpidem, a medicine used to treat insomnia.

These medicines may be affected by CIPFLOX 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 CIPFLOX.

How to take CIPFLOX

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

How much to take

Your doctor will tell you how much CIPFLOX you need to take each day. It is important that you take CIPFLOX as directed by your doctor. Do not take more than the recommended dose.

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.

The dosage for children depends on your child's body weight. Your

doctor or pharmacist will advise you on the dosing for your child.

How to take it

Swallow CIPFLOX 250 mg and 750 mg tablets whole with a glass of water or other fluid. Scored CIPFLOX 500 mg tablets may be halved and swallowed with a glass of water.

Do not take CIPFLOX with milk, yoghurt or other products very high in calcium; otherwise CIPFLOX will not be absorbed completely from the stomach.

However, if milk, yoghurt or other high calcium products are ingredients of a meal, they will NOT significantly interfere with CIPFLOX absorption.

When to take it

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.

It does not matter if you take this medicine before or after food.

If you need to take multivitamins, mineral supplements, other medicines containing iron, zinc, magnesium, aluminium or calcium, antacids, sucralfate, omeprazole, sevelamer, metoclopramide, didanosine or lanthanum carbonate, take them at least 1 to 2 hours before or 4 hours after your dose of CIPFLOX.

How long to take it

Continue taking CIPFLOX until you have finished all the tablets or for as long as your doctor tells you to.

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

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 or get worse. You might also develop resistance to the antibiotic.

Check with your doctor if you are unsure how long you should take CIPFLOX 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 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 to take your medicine, ask your pharmacist for some hints.

While you are taking CIPFLOX

Things you must do

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

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

If you are going to have a surgical or dental procedure, tell the surgeon, anaesthetist or dentist that you are taking CIPFLOX.

It may affect other medicines used during the procedure.

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

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

It may interfere with the results of some tests.

Drink plenty of water while taking CIPFLOX. This helps stop crystals forming in the urine.

If you develop diarrhoea, tell your doctor or pharmacist immediately – even if it occurs several weeks after you have stopped taking CIPFLOX. 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. CIPFLOX should be discontinued immediately.

Things you must not do

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

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

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

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 CIPFLOX immediately and tell your doctor.

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

This medicine may cause dizziness, headache, tremors, blurred vision and numbness in some patients. Your ability to drive or operate machinery may be impaired. If you drink alcohol while taking this medicine the symptoms may be worse.

Children should be careful when riding bicycles or climbing trees.

Be careful when drinking alcohol while you are given this medicine. If you drink alcohol while

being given this medicine dizziness, headache, tremors, blurred vision, numbness or light-headedness may be worse. CIPFLOX may increase the stimulatory effects of caffeine.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Information Centre (telephone 0800 POISON or 0800 764 766), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much CIPFLOX. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of an overdose may include cloudy urine.

Side effects

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

This medicine helps most people with a bacterial infection but it may have unwanted side effects in a few people.

If you are elderly you may have an increased chance of getting side effects.

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.

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
- headache, dizziness or light headedness
- flatulence
- dyspepsia (heartburn)
- loss of appetite
- itching, hives or rash

- agitation
- anxiety
- sleep disorders
- altered taste and/or smell
- swollen and/or painful joints
- muscle pain
- nonspecific pain, numbness or weakness
- feeling unwell, fever
- sweating
- burning, tingling or numbness
- feeling of skin pricking, tingling or creeping when there is no visible cause
- decreased or increased sense of feeling, especially in the skin
- looking pale
- sore throat
- red spots under the skin.
- ringing in the ear, loss of hearing, hearing impairment
- bleeding or bruising more easily than normal
- abdominal, chest or back pains
- enlarged lymph nodes
- disturbed coordination
- little or no urine
- bloody urine
- cloudy urine.

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

Photosensitivity (getting skin reactions more easily after sun exposure) can occur with CIPFLOX. Staying out of direct sunlight while on CIPFLOX will help to prevent it from happening.

Rarely, tendons, (particularly the Achilles tendon which extends from the calf to the foot) have torn or become inflamed after taking CIPFLOX – sometimes as much as several months later. Tell your doctor immediately if a tendon becomes painful and stiff, and sometimes hot, swollen and red.

Rarely, there can be a worsening of the symptoms of myasthenia gravis. This is a condition where the muscles become weak and tire easily, causing droopy eyelids, double vision, difficulty in speaking and swallowing, and sometimes muscle weakness in the arms and legs. Tell your doctor if you have any concerns.

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

Some people taking anti-diabetic medicines may experience hypoglycaemia (low blood sugar). Symptoms may include sweating, weakness, hunger, dizziness, trembling and a fast heartbeat. Tell 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. Tell your doctor if you notice any other effects.

Some of the side effects (for example, increased liver enzymes, changes in numbers of blood cells and changes in your blood pressure) can only be found when your doctor does tests from time to time to check your progress.

Do not be alarmed by these lists of possible side effects. You may not experience any of them.

After using CIPFLOX

Storage

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

If you take the tablets out of the bottle or 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 CIPFLOX 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.

Product description

What CIPFLOX looks like

CIPFLOX 250 mg: a white bi-convex round film coated tablet marked "CF" and "250" on either side of the score line on one side and "G" on the other side.

CIPFLOX 500 mg **in blisters**: a white bi-convex capsule shaped film coated tablet marked "CF" and "500" on either side of the score line on one side and "G" on the other side. Scored CIPFLOX 500 mg tablets may be halved.

CIPFLOX 500 mg **in bottles**: a white bi-convex capsule shaped film coated tablet marked "CF 500" on one side and "G" on the other side. Unscored CIPFLOX 500 mg tablets must not be halved.

CIPFLOX 750 mg: a white bi-convex capsule shaped film coated tablet marked "CF" and "750" on either side of the score line on one side and "G" on the other side.

Ingredients

Active ingredient:

CIPFLOX tablets contain the active ingredient ciprofloxacin.

Inactive ingredients:

The tablets also contain:

- microcrystalline cellulose
- maize starch
- crospovidone
- pregelatinised maize starch
- colloidal silicon dioxide
- magnesium stearate
- hypromellose
- titanium dioxide
- polydextrose
- glycerol triacetate
- macrogol.

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

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies CIPFLOX

CIPFLOX is supplied in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland
NEW ZEALAND

Telephone: 0800 579 811

Date of Information

27 January 2021
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