

NEW ZEALAND CONSUMER MEDICINE INFORMATION

CIPFLOX INFUSION

Ciprofloxacin solution for infusion, 2 mg/mL



What is in this leaflet

Please read this leaflet carefully before you are started on CIPFLOX INFUSION.

This leaflet answers some common questions about CIPFLOX INFUSION.

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 being given CIPFLOX INFUSION against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

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

What CIPFLOX INFUSION is used for

CIPFLOX INFUSION is used to treat infections of the:

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

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

CIPFLOX INFUSION contains the active ingredient ciprofloxacin. It belongs to a group of antibiotics called quinolones.

It works 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.

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

CIPFLOX INFUSION is used in a hospital environment only.

This medicine is not addictive.

Before you are given CIPFLOX INFUSION

When you must not be given it

You must not be given CIPFLOX INFUSION if you have an allergy to:

- any medicine containing ciprofloxacin or other quinolone antibiotics, including nalidixic acid, moxifloxacin and norfloxacin
- 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.

You must not be given CIPFLOX INFUSION if you are taking a medicine called tizanidine (a muscle relaxant used to treat

spasticity associated with multiple sclerosis, injury or disease of the spinal cord).

CIPFLOX INFUSION can interfere with tizanidine and this can lead to undesirable side effects.

You must not be given 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, your doctor, pharmacist or nurse should dispose it.

The contents of the infusion bag are not to be used if it is cloudy or has little specks in it.

If you are not sure whether you should be started on this medicine, talk to your doctor.

Before you are started on 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:

- 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 INFUSION 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 INFUSION is not recommended during breast feeding as CIPFLOX INFUSION is excreted into the breast milk. Talk to you doctor about whether you should temporarily stop breastfeeding while being given CIPFLOX INFUSION.

If you have not told your doctor about any of the above, tell them before you are started on CIPFLOX INFUSION.

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 given CIPFLOX INFUSION.

Some medicines may interfere with CIPFLOX INFUSION. These include:

- probenecid, a medicine used to treat gout
- 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
- omeprazole, a medicine used to treat heartburn
- 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
- metoclopramide, a medicine used to treat slow gastric emptying in people with diabetes
- 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 INFUSION 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.

How CIPFLOX INFUSION is given

CIPFLOX INFUSION is given as a slow injection (over 60 minutes) into a vein, usually as a drip, by a doctor or a nurse.

CIPFLOX INFUSION is incompatible with alkaline drugs.

How much is given

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

They may differ from the information contained in this leaflet.

Your doctor will decide on the dose and length of time that you will receive CIPFLOX INFUSION. Normally your doctor will put you on antibiotic tablets as soon as possible; but for difficult infections longer intravenous therapy may be required.

If you have not been given the next dose, tell the doctor or nurse on duty as soon as possible.

How long you will be given it

It is important that you finish the course of treatment even if you begin to feel better after a few days. If your treatment is stopped too soon your infection may not be completely cured and the symptoms of the infection may return or get worse. You might also develop resistance to the antibiotic.

If you have any further questions about the use of this medicine, ask your doctor or pharmacist.

While CIPFLOX INFUSION is given

Things you must do

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

Tell any other doctors, dentists, and pharmacists who treat you that you are given this medicine.

If you are going to have a surgical or dental procedure, tell the surgeon, anaesthetist or dentist that you are given this medicine.

It may affect other medicines used during the procedure.

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

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

It may interfere with the results of some tests.

If you develop diarrhoea, tell your doctor, nurse or pharmacist immediately – even if it occurs several weeks after you have finished your treatment with CIPFLOX INFUSION. 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 INFUSION should be discontinued immediately.

Things to be careful of

Avoid excessive exposure to direct sunlight. Your skin may become more prone to sunburn. If such a reaction occurs, tell your doctor immediately.

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

This medicine may cause dizziness, headache, tremors, blurred vision, numbness or 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. 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 are given too much (overdose)

Immediately tell the doctor or nurse if you think that you or anyone else may have been given too much CIPFLOX INFUSION. 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 given CIPFLOX INFUSION.

This medicine helps most people with serious infections, 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.

CIPFLOX INFUSION can cause redness, pain, oedema, hypersensitivity and inflammation at the injection site.

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

- nausea or vomiting
- rash, hives or itching
- headache, dizziness or light headedness
- flatulence
- dyspepsia (heartburn)
- loss of appetite
- 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 of the hands or feet (pins and needles)
- 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.

The above list includes some of the more common side effects of your medicine.

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 or blistering of the skin
- fast or irregular heart beats
- wheezing, difficulty breathing or chest tightness
- shortness of breath
- swelling of the face, lips, mouth or throat which may cause difficulties in swallowing or breathing
- seizures, fits or convulsions
- tremors

- confusion/disorientation, dizziness, hallucinations, abnormal dreams, depression and psychotic reactions (even progressing to self-injuring behaviour or thoughts of suicide)
- visual disturbance
- ringing in the ear or hearing loss
- yellowing of the skin and eyes, also called jaundice
- dark urine or pale stools
- inflammation of the bowel or abdominal cramps
- joint/muscle pain (arthritis) or cramping
- anaphylactic reactions
- unusual bleeding or bruising
- bleeding or bruising more easily than normal
- fainting
- diarrhoea which may be watery or bloody with stomach pain and fever - even if it occurs several weeks after taking your tablets
- 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 that may need urgent medical attention. Photosensitivity (getting skin reactions more easily after sun exposure) can occur with ciprofloxacin. Staying out of direct sunlight while on CIPFLOX INFUSION 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 INFUSION – 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 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. 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 you have been given CIPFLOX INFUSION

When treatment is to be stopped, your prescribing doctor may need to alter the dose of other medicine(s) accordingly and monitor your condition.

Each bag of CIPFLOX INFUSION is to be used once only. Any unused portion remaining in the bag must be discarded.

Storage

CIPFLOX INFUSION will be stored in the pharmacy or on the ward. The infusion bag is kept cool, where the temperature stays below 25°C. The infusion bag should not be stored in the refrigerator or freezer. The infusion bag should be stored in

the outer overwrap in order to protect it from light.

If you have any further questions on CIPFLOX INFUSION, or are unsure of the information given above, please see your doctor or nurse, who will be able to assist you.

Product description

What it looks like

100 mL bag of clear, colourless to slightly yellow solution containing 200 mg ciprofloxacin.

Ingredients

Active ingredient:
CIPFLOX INFUSION contains 200 mg of ciprofloxacin as the active ingredient.

Inactive ingredients:
It also contains:

- lactic acid
- glucose
- hydrochloric acid
- water for injection.

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 this medicine

CIPFLOX INFUSION is supplied in New Zealand by:

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

Telephone: 0800 579 811

Date of Information

23 September 2020
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