

## CIPFLOX

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



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### What is in this leaflet

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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.

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### What CIPFLOX is used for

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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.

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

**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.

There is no evidence that CIPFLOX is addictive.

CIPFLOX is available only with a doctor's prescription.

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### Before you take CIPFLOX

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**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 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.** CIPFLOX is excreted into the breastmilk. Your doctor will decide 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.**

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

**Tell your doctor if you have or have had any of the following medical conditions:**

- if you suffer from fits (seizures, convulsions), have had a stroke, or have 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.
- if you have a fast or irregular heartbeat

(arrhythmias). CIPFLOX may increase the risk of arrhythmias, especially in the elderly or patients with low potassium levels

- if you have myasthenia gravis, a condition where the muscles become weak. CIPFLOX can make the symptoms of this condition worse
- if you have a history of tendon disorders with the use of quinolones (such as naladixic acid, norfloxacin or moxifloxacin).

**If you have not told your doctor about any of the above, tell him/her before you start taking CIPFLOX.**

### ***Taking other medicines***

**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.

**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 CIPFLOX may interfere with each other. These include:

- theophylline, a medicine used to treat asthma
- warfarin, a medicine used to prevent blood clots
- glibenclamide, a medicine used to treat diabetes
- cyclosporin, a medicine used in organ transplantation
- NSAIDs (non-steroidal anti-inflammatory drugs), medicines used to relieve pain, swelling, arthritis and other inflammatory conditions.
- methotrexate, a medicine used to treat certain types of cancers, severe psoriasis and severe rheumatoid arthritis

- duloxetine, a medicine used to treat depression and stress urinary incontinence
- caffeine and methylxanthines, found in some medicines and in drinks such as coffee, tea, cola.
- clozapine, a medicine used to treat schizophrenia
- ropinirole, a medicine used to treat Parkinson's disease and restless leg syndrome
- lidocaine, a local anaesthetic used to numb pain and cause a loss of sensation
- sildenafil, a medicine used for erectile dysfunction.
- medicines used to treat a fast or irregular heartbeat (arrhythmias).

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.

**Some medicines may interfere with the absorption of CIPFLOX. These include:**

- multivitamins, mineral supplements and other medicines containing iron, zinc, magnesium, aluminium or calcium
- antacids used for indigestion
- 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
- sevelamer, a medicine used to treat high blood levels of phosphates in patients with kidney disease who are on dialysis
- metoclopramide, a medicine used to relieve nausea and vomiting
- didanosine, a medicine used to treat viral infections.

You can still take these medicines while you're taking CIPFLOX. However, you must take CIPFLOX either 1 to 2 hours before or at least 4 hours after taking any of these

preparations to make sure there's no problem with absorption.

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

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## **How to take CIPFLOX**

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**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 box, 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.

### ***How to take it***

Swallow the tablets whole with a glass of water or other fluid. CIPFLOX can be taken with or without food.

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 interfere with CIPFLOX absorption.

### ***When to take it***

Taking your medicine at the same time each day may help you to remember to take it regularly. If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

**If you need to take an antacid, take it at least 1 to 2 hours before or 4 hours after your dose of CIPFLOX.**

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

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 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 missed dose 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 take too much (overdose)***

**Immediately telephone your doctor or the National Poisons Information Centre (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 CIPFLOX. 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 using CIPFLOX**

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### ***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 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 because you are feeling better, unless your doctor has told you to. 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 in some patients. Your ability to drive or operate machinery may be impaired. If you drink alcohol while taking this medicine the dizziness may be worse.

CIPFLOX 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 CIPFLOX.**

This medicine helps most people with a bacterial infection 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 attention if you get some of the side effects.

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

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

- nausea
- diarrhoea
- headache
- dizziness or light headedness

- stomach pains
- vomiting
- flatulence
- dyspepsia (heartburn)
- loss of appetite
- itching or rash
- agitation, anxiety
- sleep disorders
- altered taste
- joint pain or swollen joints
- unspecific pain
- feeling unwell, fever.

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

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

- severe skin rashes, peeling or blistering of the skin
- swelling of the face, lips, mouth or throat
- unusual bleeding or bruising
- fainting
- yellowing of the skin and eyes, also called jaundice
- severe watery or bloody diarrhoea, with stomach pain and fever - even if it occurs several weeks after taking your tablets
- fits (seizures, convulsions) and tremors
- irregular heart beats
- confusion, nightmares, hallucinations, and psychotic reactions (even progressing to self-endangering behaviour)
- wheezing or difficulty in breathing
- visual disturbances
- ringing in the ear, loss of hearing
- bleeding or bruising more easily than normal
- abdominal pain or cramps. Very rarely this can progress to a serious condition accompanied by fever and fatigue.

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

Photosensitivity (getting sunburnt very easily) can occasionally occur with CIPFLOX. It is a temporary condition and staying out of direct sunlight while on CIPFLOX will 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 6 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.

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.

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

**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.

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## After using CIPFLOX

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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 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 damp 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.**

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## Product description

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### 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: 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.

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

CIPFLOX tablets contains the active ingredient ciprofloxacin.

The tablets also contain:

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

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

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## **If you want to know more**

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

### ***Who supplies CIPFLOX***

Distributed in New Zealand by:

Mylan New Zealand Ltd,  
PO Box 11183,  
Ellerslie,  
Auckland.

Telephone: (09) 579 2792

### ***Date of Information***

19 August 2011  
(Based on datasheet dated  
3 September 2010)