

Package leaflet: Information for the patient

Cifloxager 250 mg Film-coated Tablets

Cifloxager 500 mg Film-coated Tablets

(ciprofloxacin)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again
- If you have further questions, ask your doctor or pharmacist
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Cifloxager is and what it is used for
2. What you need to know before you take Cifloxager
3. How to take Cifloxager
4. Possible side effects
5. How to store Cifloxager
6. Contents of the pack and other information

1. What Cifloxager is and what it is used for

Cifloxager is an antibiotic belonging to the fluoroquinolone family. The active substance is ciprofloxacin. Ciprofloxacin works by killing bacteria that cause infections.

Adults:

Cifloxager is used in adults to treat the following bacterial infections:

- Respiratory tract infections
- Long lasting or recurring ear or sinus infections
- Urinary tract infections
- Genital tract infections in men and women
- Gastro-intestinal tract infections and intra-abdominal infections
- Skin and soft tissue infections
- Bone and joint infections
- To prevent infections due to the bacterium *Neisseria meningitidis*
- Anthrax inhalation exposure

Ciprofloxacin may be used in the management of patients with low blood cell counts (neutropenia) who have a fever that is suspected to be due to a bacterial infection.

Children and adolescents

Cifloxager is used in children and adolescents, under specialist medical supervision, to treat the following bacterial infections:

- Lung and bronchial infections in children and adolescents suffering from cystic fibrosis
- Complicated urinary tract infections, including infections that have reached the kidneys (pyelonephritis)
- Anthrax inhalation exposure

Cifloxager may also be used to treat other specific severe infections in children and adolescents when your doctor considers this necessary

2. What you need to know before you take Cifloxager

Do not take Cifloxager

- if you are allergic to ciprofloxacin or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to quinolone antibiotics
- if you are taking tizanidine, for treatment of muscle spasms.

Warnings and precautions

Thoughts of suicide and worsening of your depression

If you are depressed and/or have severe thought disturbances, you may sometimes have thoughts of harming or killing yourself. These thoughts may be increased with Cifloxager treatment.

This is a rare but very serious side-effect.

Tell your doctor immediately if you experience any of these thoughts.

Heart problems

Caution should be taken when using this kind of medicine, if you were born with or have family history of prolonged QT interval (seen on ECG, electrical recording of the heart), have salt imbalance in the blood (especially low level of potassium or magnesium in the blood), have a very slow heart rhythm (called 'bradycardia'), have a weak heart (heart failure), have a history of heart attack (myocardial infarction), you are female or elderly or you are taking other medicines that result in abnormal ECG changes (see section '**Other medicines and Cifloxager**').

Talk to your doctor or pharmacist before taking Cifloxager if you:

- have ever had kidney problems because your treatment may need to be adjusted
- have myasthenia gravis (a type of muscle weakness)
- have a history of tendon disorders e.g. tendonitis or ruptured tendons during previous treatment with quinolone antibiotics such as ciprofloxacin
- have diabetes because you may experience a risk of hypoglycaemia (low blood sugar)

While taking Cifloxager

Tell your doctor immediately, if any of the following occurs **while taking Cifloxager**. Your doctor will decide whether treatment with Cifloxager needs to be stopped.

- **Severe, sudden allergic reaction** (an anaphylactic reaction/shock, angio-oedema). Even with the first dose, there is a small chance that you may experience a severe allergic reaction with the following symptoms: tightness in the chest, feeling dizzy, sick or faint, or experiencing dizziness when standing up. **If this happens, stop taking Cifloxager and contact your doctor immediately.**

- **Pain and swelling in the joints and tendinitis** may occur occasionally, particularly if you are elderly and are also being treated with corticosteroids. At the first sign of any pain or inflammation stop taking Cifloxager and rest the painful area. Avoid any unnecessary exercise, as this might increase the risk of a tendon rupture. Tendon inflammation and ruptures may occur even up to several months after you stop taking Cifloxager.
- If you suffer from **epilepsy** or other **neurological conditions** such as cerebral ischemia or stroke, you may experience side effects associated with the central nervous system. If this happens, stop taking Cifloxager and contact your doctor immediately.
- You may experience **psychiatric reactions** the first time you take Cifloxager. If you suffer from **depression** or **psychosis**, your symptoms may become worse under treatment with Cifloxager. If this happens, stop taking Cifloxager and contact your doctor immediately.
- You may experience symptoms of neuropathy such as pain, burning, tingling, numbness and/or weakness. If this happens, stop taking Cifloxager and contact your doctor immediately.
- **Diarrhoea** may develop while you are taking antibiotics, including Cifloxager, or even several weeks after you have stopped taking them. If it becomes severe or persistent or you notice that your stool contains blood or mucus, stop taking Cifloxager immediately, as this can be life-threatening. Do not take medicines that stop or slow down bowel movements and contact your doctor.
- Tell the doctor or laboratory staff that you are taking Cifloxager if you have to provide a **blood or urine sample**.
- Crystalluria (crystals in the urine) related to the use of ciprofloxacin has been reported. You need to drink plenty of water to avoid crystalluria.
- Cifloxager may cause **liver damage**. If you notice any symptoms such as loss of appetite, jaundice (yellowing of the skin), dark urine, itching, or tenderness of the stomach, stop taking Cifloxager and contact your doctor immediately.
- Cifloxager may cause a reduction in the number of white blood cells and your **resistance to infection may be decreased**. If you experience an infection with symptoms such as fever and serious deterioration of your general condition, or fever with local infection symptoms such as sore throat/pharynx/mouth or urinary problems you should see your doctor immediately. A blood test will be taken to check possible reduction of white blood cells (agranulocytosis). It is important to inform your doctor about your medicine.
- Tell your doctor if you or a member of your family is known to have a deficiency in glucose-6- phosphate dehydrogenase (G6PD), since you may experience a risk of anaemia (a disorder of the blood, where there are less red blood cells which may cause you to feel tired, or breathless with pale skin) with Cifloxager.
- Your skin becomes more **sensitive to sunlight or ultraviolet (UV) light** when taking Cifloxager. Avoid exposure to strong sunlight, or artificial UV light such as sunbeds.

- If your eyesight becomes impaired or if your eyes seem to be otherwise affected, consult an eye specialist immediately.

Other medicines and Cifloxager

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

You must tell your doctor if you are taking other medicines that can alter your heart rhythm: medicines that belong to the group of anti-arrhythmics (e.g. quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, dofetilide, ibutilide), tricyclic antidepressants, some antimicrobials (that belong to the group of macrolides), some antipsychotics.

Do not take Cifloxager together with tizanidine, because this may cause side effects such as low blood pressure and sleepiness (see Section 2: "**Do not take Cifloxager**").

The following medicines are known to interact with Cifloxager in your body. Taking Cifloxager together with these medicines can influence the therapeutic effect of those medicines. It can also increase the probability of experiencing side effects.

In particular, inform your doctor if you are taking any of the following medicines:

- theophylline, for asthma
- phenytoin, for epilepsy
- metoclopramide, an anti-sickness medicine
- glibenclamide, antidiabetic medicine
- anticoagulants to thin the blood e.g. warfarin, acenocoumarol, phenprocoumon, fluindione
- ciclosporin (for skin conditions, rheumatoid arthritis and in organ transplantation); your doctor may need to take blood samples twice a week.
- probenecid, to treat gout
- medicine containing clozapine (an antipsychotic) or ropinirole (for Parkinson's disease)
- methotrexate (for certain types of cancer, psoriasis, rheumatoid arthritis)

Cifloxager may **increase** the levels of the following medicines in your blood:

- pentoxifylline (for circulatory disorders)
- duloxetine (for depression, anxiety, pain and stress incontinence)
- olanzapine (an antipsychotic)
- lidocaine given as an injection (an anaesthetic often used in surgical procedures)
- sildenafil (for impotence)
- caffeine

Cifloxager can increase the level of the following substances in the blood:

- Agomelatine,
- *Zolpidem*

Some medicines **reduce** the effect of Cifloxager. Tell your doctor if you take or wish to take:

- antacids, mineral supplements or any other medicines containing calcium, magnesium, aluminium or iron.
- sucralfate (for stomach ulcers)

- medicines used to reduce the amount of phosphate that is absorbed from food in your gut (e.g. sevelamer or lanthanum carbonate)
- medicines that also contain an antacid in the same formulation to protect them and stop them from breaking down in the gut (e.g. didanosine tablets used in HIV)
- omeprazole (for gastric reflux often known as heartburn, stomach or intestinal ulcers)

If it is important for you to take these medicines or supplements at the same time as taking Cifloxager, take Cifloxager about two hours before or no sooner than four hours after them.

Cifloxager with food and drink

Do not take dairy products or fortified drinks (e.g. milk, yoghurt, calcium fortified orange juice) at the same time as taking Cifloxager, as the effect of the medicine may be reduced.

Pregnancy and breast-feeding

Cifloxager should not be taken by pregnant or breast-feeding mothers unless on the advice of your doctor. This type of antibiotic may cause pain and swelling in the developing joints of children.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Do not drive or operate machines if you feel dizzy, suffer from loss of hearing or blurred vision. Alcohol can worsen these effects.

Cifloxager contains glucose and sorbitol

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Cifloxager

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

It is important that you complete the course of treatment as directed by your doctor even if you feel better.

Your doctor will explain to you exactly how much Cifloxager you will have to take as well as how often and for how long. This will depend on the type of infection you have and how bad it is. Treatment usually for 5-21 days, but may take longer for severe infections.

If you have a severe infection or one that is caused by more than one type of bacterium, you may be given additional antibiotic treatment in addition to Cifloxager

If you have kidney problems, your doctor may give you a lower dose of Cifloxager.

Some patients may need regular blood tests to check the level of Cifloxager in their blood.

Swallow the tablets with a full glass of water.

Do try to take the tablets around the same time every day.

You can take the tablets at mealtimes or between meals.

If you take more Cifloxager than you should

If you take more Cifloxager than you should, contact your doctor or local accident and emergency department immediately. If possible take your tablets or the box with you to show the doctor. You may experience dizziness, shaking, headache, tiredness, fits, hallucinations (seeing, feeling or hearing things that are not there), confusion, stomach pain, feeling/being sick, passing urine which may be cloudy or contain blood or crystals.

If you forget to take a dose of Cifloxager

If you forget to take a dose of Cifloxager, take it as soon as you remember. If it is almost time for your next dose though, do not take a double dose to make up for the forgotten tablet, just carry on as before.

If you stop taking Cifloxager

Do not stop taking Cifloxager without talking to your doctor, even if you feel better. It is important you take the full course of Cifloxager prescribed by your doctor.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you notice any of the following, stop taking Cifloxager and contact your doctor straight away or go to the nearest hospital emergency department:

Uncommon (may affect up to 1 in 100 people):

- Candida or yeast infection 'thrush' (which is due to fungal overgrowth due to a reduction in the normal bacteria present in the body)
- Yellowing of the skin or eyes (due to raised liver enzymes or bilirubin, a yellow breakdown product of red blood cells)

Rare (may affect up to 1 in 1,000 people):

- Colitis (inflammation of the colon with severe diarrhoea and blood in the stools)
- Reduced white blood cell count which can lead to more infections than usual, causing fever, sore throat, or swollen glands.
- Feeling anxious, confused and depressed and you feel you want to physically harm yourself or you actually do physically harm yourself.
- Fits
- Loss of hearing
- Liver problems, jaundice yellowing of the skin or whites of the eyes, hepatitis, dark urine and pale stools
- Kidney problems which may be severe, (blood in the urine, inflammation causing pain when passing water)

Very rare (may affect up to 1 in 10,000 people):

- Symptoms of psychosis (i.e. severe thought disturbances)

- If you develop a red rash which may be raised with ulcers or blisters and/or peeling skin (as this could be the potentially fatal Stevens-Johnson syndrome or toxic epidermal necrolysis)
- If you develop itchy swollen skin, swelling of the face, throat or tongue, tightness of the chest and difficulty breathing (anaphylactic reaction or anaphylactic shock).
- A type of reduced red blood cell count causing shortage of breath, tiredness, yellowing of skin and eyes (haemolytic anaemia)
- If you feel tired and weak and bruise more easily or develop pin-prick red dots under the skin (petechiae) and suffer unexplained bleeding (pancytopenia)
- Pancreatitis (pain in stomach and back with feeling and being sick which is worse after eating)
- Severe liver problems, with yellowing of skin and eyes, pain in the upper abdomen, feeling and being sick and generally feeling unwell.(hepatic necrosis)
- Muscle weakness, tendon inflammation, tendon rupture – especially of the large tendon at the back of the ankle (Achilles tendon) (see section 2).
- Pressure on the brain (intracranial pressure) which may cause severe headache, feeling and being sick, problems with moving eyes in same direction and changes in level of consciousness.
- Worsening of symptoms of myasthenia gravis (a type of muscle weakness)

Not known (frequency cannot be estimated from the available data):

- Troubles associated with the nervous system such as pain, burning, tingling, numbness and/or weakness in extremities (polyneuropathy)
- Abnormal fast heart rhythm, life-threatening irregular heart rhythm, alteration of the heart rhythm (called ‘prolongation of QT interval’, seen on ECG, electrical activity of the heart)
- Hypersensitivity reaction called DRESS (Drug Reaction with Eosinophilia and Systemic Symptoms)

These are very serious side-effects requiring immediate attention which are potentially life-threatening.

Other side effects include:

Common (affecting fewer than 1 in 10 people)

- Diarrhoea and feeling sick
- Joint pains in children

Uncommon (affecting fewer than 1 in 100 people):

- A raised number of a special type of white blood cell which may show up in blood tests
- Loss of appetite
- Feeling restless, agitated, hyperactive
- Headache
- Dizziness
- Sleep problems
- Taste changes (usually returns to normal when treatment stops)
- Stomach or gut pains, being sick, indigestion, wind
- Raised liver enzymes or bilirubin in the blood

- Red itchy swollen skin, nettle rash or hives
- Joint pain
- Chest and back pain
- Kidney problems causing difficulty/pain passing urine
- Fever, pain, feeling weak
- Increase in blood alkaline phosphatase (a certain substance in the blood), increased liver enzymes and bilirubin, which would be seen in blood test results.

Rare (may affect up to 1 in 1,000 people):

- Allergic reaction which may cause sudden skin irritation and swelling
- Raised or decreased blood glucose (sugar) levels
- Feeling anxious, confused or disorientated
- Abnormal vivid dreams, hallucinations (seeing, hearing or feeling things that are not real)
- An increased or decreased sensitivity to touch
- Trembling, tingling sensation
- Vertigo, drowsiness
- Eyesight changes (e.g. double vision)
- Ringing in the ears
- A racing heart beat
- Feeling flushed, low blood pressure, fainting
- Breathlessness, wheezing
- Sensitivity of the skin to sunlight, blistering skin
- Muscle pain or cramps, increased muscle tone, swollen joints
- Blood or 'crystals' in the urine
- Sweating, swollen ankles
- Change in amylase or prothrombin levels in the blood.

Very rare (may affect up to 1 in 10,000 people):

- Migraine,
- Feeling unsteady when walking
- Changes in colour vision, change in the sense of smell or hearing
- Inflamed blood vessels (vasculitis)
- Small, pin-point bleeding under the skin (petechiae)
- Muscle weakness
- Sore, swollen, painful tendons which very rarely may tear (more likely in elderly patients and those on corticosteroid treatment)

Not known (frequency cannot be estimated from the available data)

- Increased clotting time in people taking warfarin or other oral anti-coagulants (to thin the blood)
- Increased feeling or sensitivity, especially in the skin (hyperesthesia)
- Feeling highly excited (mania) or feeling great optimism and overactivity (hypomania)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL- Dublin 2; Tel: +353 1 6764971; Fax: + 353 1 6762517; Website: www.hpra.ie; e-mail: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cifloxager

Keep out of the sight and reach of children.

Do not use Cifloxager after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Cifloxager tablets contain

- Each film-coated tablet contains ciprofloxacin hydrochloride equivalent to 250 mg or 500 mg of the active substance ciprofloxacin.
- The other ingredients are microcrystalline cellulose, maize starch, crospovidone, pregelatinised maize starch, magnesium stearate and colloidal anhydrous silica. The tablet coating contains hypromellose, titanium dioxide (E171). The film coating contains polydextrose (containing glucose and sorbitol (E420)) (see section 2, 'Cifloxager contains glucose and sorbitol'), triacetin and macrogol.

What Cifloxager tablets look like and contents of the pack

Cifloxager tablets are white, film-coated tablets. The 250 mg tablets are round and marked "CF | 250" on one side and "G" on the other. The 500 mg tablets are capsule-shaped and marked "CF | 500" on one side and "G" on the other.

Cifloxager is available in blister packs of 10 and 20 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder:

McDermott Laboratories Limited,
trading as Gerard Laboratories,
35/36 Baldoyle Industrial Estate
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Dublin 13
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Manufacturers:

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