

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. It only works with specific strains of bacteria.

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 white blood cell counts (neutropenia) who have a fever that is suspected to be due to a bacterial infection.

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 ciprofloxacin.

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 (acute 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 (see section 2 ‘Other medicines and Cifloxager’).

Warnings and precautions

Before taking this medicine

You should not take fluoroquinolone/quinolone antibacterial medicines, including Cifloxager, if you have experienced any serious adverse reaction in the past when taking a quinolone or fluoroquinolone. In this situation, you should **inform your doctor as soon as possible**.

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
- suffer from epilepsy (fits) or other neurological conditions
- have myasthenia gravis (a type of muscle weakness) because symptoms can be exacerbated
- 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 with ciprofloxacin
- 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)
- have been diagnosed with an enlargement or "bulge" of a large blood vessel (aortic aneurysm or large vessel peripheral aneurysm).
- have experienced a previous episode of aortic dissection (a tear in the aorta wall).
- if you have been diagnosed with leaking heart valves (heart valve regurgitation).
- have a family history of aortic aneurysm or aortic dissection or congenital heart valve disease, or other risk factors or predisposing conditions (e.g. connective tissue disorders such as Marfan syndrome, or Ehlers-Danlos syndrome, Turner syndrome, Sjögren's syndrome (an inflammatory autoimmune disease), or vascular disorders such as Takayasu arteritis, giant cell arteritis, Behcet's disease, high blood pressure, or known atherosclerosis, rheumatoid arthritis (a disease of the joints) or endocarditis (an infection of the heart).

- If you feel sudden, severe pain in your abdomen, chest or back, which can be symptoms of aortic aneurysm and dissection, go immediately to an emergency room. Your risk may be increased if you are being treated with systemic corticosteroids.

- If you start experiencing a rapid onset of shortness of breath, especially when you lie down flat in your bed, or you notice swelling of your ankles, feet or abdomen, or a new onset of heart palpitations (sensation of rapid or irregular heartbeat), you should inform a doctor immediately.

For the treatment of some genital tract infections, your doctor can prescribe another antibiotic in addition to ciprofloxacin. If there is no improvement in symptoms after 3 days of treatment, please consult your doctor.

When taking this medicine

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.

- **Prolonged, disabling and potentially irreversible serious side effects**
Fluoroquinolone/quinolone antibacterial medicines, including Cifloxager have been associated with very rare but serious side effects, some of them being long lasting (continuing months or years), disabling or potentially irreversible. This includes tendon, muscle and joint pain of the upper and lower limbs, difficulty in walking, abnormal sensations such as pins and needles, tingling, tickling, numbness or burning (paraesthesia), sensory disorders including impairment of vision, taste and smell, and hearing, depression, memory impairment, severe fatigue, and severe sleep disorders.

If you experience any of these side effects after taking Cifloxager, **contact your doctor immediately** prior to continuing treatment. You and your doctor will decide on continuing the treatment considering also an antibiotic from another class.

- **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, chest pain, shortness of breath, feeling dizzy, sick or faint, or experiencing dizziness when standing up. **If this happens, stop taking Cifloxager and contact your doctor or medical emergencies immediately.**
- **Pain and swelling in the joints and inflammation or rupture of tendons** may occur rarely. Your risk is increased if you are elderly (above 60 years of age), have received an organ transplant, have kidney problems or if you are being treated with corticosteroids. Inflammation and ruptures of tendons may occur within the first 48 hours of treatment and even up to several months after stopping of Cifloxager therapy. At the first sign of any pain or inflammation of a tendon (for example in your ankle, wrist, elbow, shoulder or knee), stop taking Cifloxager, **contact your doctor** and rest the painful area. Avoid any unnecessary exercise as this might increase the risk of a tendon rupture.
- 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. In rare cases, depression or psychosis can progress to thoughts of suicide, suicide attempts or completed suicide. If depression, psychosis, suicide-related thoughts, or behaviour occur, contact your doctor immediately.
- You may rarely experience symptoms of **nerve damage (neuropathy)** such as pain, burning, tingling, numbness and/or weakness especially in the feet and legs or hands and arms. If this happens, stop taking Cifloxager and **inform your doctor immediately** in order to prevent the development of potentially irreversible condition.
- Quinolone antibiotics may cause an increase **of your blood sugar levels** above normal levels (hyperglycaemia), **or lowering of your blood sugar levels below normal levels, potentially leading to loss of consciousness** (hypoglycaemic coma) **in severe cases (see section 4). This is important for people who have diabetes.** If you suffer from diabetes, your blood sugar should be carefully monitored.
- **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.**
- If you suffer from **kidney problems**, tell the doctor because your dose may need to be adjusted.
- 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 or other breathing problems)
- tizanidine (for muscle spasticity in multiple sclerosis)
- olanzapine (an antipsychotic)
- clozapine (an antipsychotic)
- ropinirole (for Parkinson's disease)
- phenytoin, for epilepsy
- metoclopramide, an anti-sickness medicine
- glibenclamide, antidiabetic medicine
- Vitamin K antagonists (e.g. warfarin, acenocoumarol, phenprocoumon, fluindione) or other oral anticoagulants (to thin the blood)
- 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)

- zolpidem (for sleep disorders)

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
- agomelatine (for depression)

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.

Do not take Cifloxager during breast-feeding because ciprofloxacin is excreted in breast milk and can be harmful for your child.

Driving and using machines

Cifloxager may make you feel less alert. Some neurological adverse events can occur. Therefore, make sure you know how you react to Cifloxager before driving a vehicle or operating machinery. If in doubt, talk to your doctor.

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 not** chew and do not crush the tablets. If you are not able to swallow the tablet, please inform your doctor, so that he could prescribe another formulation more suitable for you.
- Do try to take the tablets around the same time every day.
- You can take the tablets at mealtimes or between meals. Any calcium you take as part of a meal will not seriously affect uptake. However, **do not** take Cifloxager tablets with dairy products such as milk or yoghurt or with fortified fruit-juices (e.g. orange juice containing added calcium).

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 Cifloxager and it is:

- **6 hours or more** until your next scheduled dose, take your missed dose right away. Then take the next dose at your regular time.
- **less than 6 hours** until your next scheduled dose, do not take the missed dose. Take the next dose at your regular time.

Do not take a double dose to make up for a forgotten dose. Be sure to complete your course of treatment.

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 stop taking this medicine 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 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.

The following section contains the most serious side effects that you can recognize yourself:

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

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

- Seizure (see Section 2: Warnings and precautions)

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

- Severe, sudden allergic reaction with symptoms such as tightness in the chest, feeling dizzy, sick or faint, or experience dizziness when standing up (anaphylactic reaction/shock) (see Section 2: Warnings and precautions)

- Muscle weakness, inflammation of the tendons which could lead to rupture of the tendon, particularly affecting the large tendon at the back of the ankle (Achilles tendon) (see Section 2: Warnings and precautions)

- A serious life-threatening skin rash, usually in the form of blisters or ulcers in the mouth, throat, nose, eyes and other mucous membranes such as genitals which may progress to widespread blistering or peeling of the skin (Stevens-Johnson syndrome, toxic epidermal necrolysis).

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

- Unusual feelings of pain, burning tingling, numbness or muscle weakness in the extremities (neuropathy) (see Section 2: Warnings and precautions)

- chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome

- A drug reaction that causes rash, fever, inflammation of internal organs, hematologic abnormalities and systemic illness (DRESS Drug Reaction with Eosinophilia and Systemic Symptoms, AGEP Acute Generalised Exanthematous Pustulosis).

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

Other side effects which have been observed during treatment with Cifloxager are listed below by how likely they are:

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
- fungal superinfections
- decreased appetite
- Feeling restless, agitated, hyperactive
- Headache
- Dizziness
- Sleep problems

- Taste changes (usually returns to normal when treatment stops)
- Stomach or abdominal pains, digestive problems such as being sick, indigestion/heartburn, wind
- Raised liver enzymes or bilirubin in the blood
- Red itchy swollen skin, nettle rash or hives
- joint pain in adults
- Chest and back pain
- Kidney problems causing difficulty/pain passing urine
- pains in your muscles and bones, 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 of the skin and mucous membranes (angio-oedema) (see Section 2: Warnings and precautions)
- inflammation of the bowel (colitis) linked to antibiotic use (can be fatal in very rare cases) (see Section 2: Warnings and precautions)
- Raised (hyperglycaemia) or decreased (hypoglycaemia) blood glucose (sugar) levels (see Section 2: Warnings and precautions)
- Feeling anxious, confused or disorientated
- Abnormal vivid dreams, hallucinations (seeing, hearing or feeling things that are not real) depression (potentially leading to thoughts of suicide, suicide attempts, or completed suicide) (see Section 2: Warnings and precautions)
- An increased or decreased sensitivity to touch
- Trembling, tingling sensation
- Vertigo, drowsiness
- Eyesight changes (e.g. double vision) (see Section 2: Warnings and precautions)
- Ringing in the ears (tinnitus), loss of hearing, impaired hearing
- A racing heart beat
- Feeling flushed, low blood pressure, fainting
- Breathlessness, wheezing
- liver disorders, jaundice (cholestatic icterus), or hepatitis
- Sensitivity of the skin to sunlight, blistering skin
- Muscle pain or cramps, increased muscle tone, swollen joints
- Kidney failure, blood or 'crystals' in the urine, urinary tract inflammation
- Sweating, swollen ankles
- increased levels of the enzyme amylase

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

- a special type of reduced red blood cell count (haemolytic anaemia); a dangerous drop in a type of white blood cells (agranulocytosis) (see Section 2: Warnings and precautions); a drop in the number of red and white blood cells and platelets (pancytopenia), which may be fatal; and bone marrow depression, which may also be fatal
- allergic reaction called serum sickness-like reaction (see Section 2: Warnings and precautions)
- mental disturbances (psychotic reactions potentially leading to thoughts of suicide, suicide attempts, or completed suicide) (see Section 2: Warnings and precautions)
- Migraine, Feeling unsteady when walking (gait disturbance), pressure on the brain (intracranial pressure and pseudotumor cerebri)
- Changes in colour vision, change in the sense of smell or hearing

- Inflamed blood vessels (vasculitis)
- pancreatitis
- death of liver cells (liver necrosis) very rarely leading to life-threatening liver failure (see Section 2: Warnings and precautions)
- Small, pin-point bleeding under the skin (petechiae)
- worsening of symptoms of myasthenia gravis (a type of muscle weakness)
- Sore, swollen, painful tendons which very rarely may tear, particularly affecting the large tendon at the back of the ankle (Achilles tendon) (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)
- Feeling highly excited (mania) or feeling great optimism and overactivity (hypomania)
- 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)
- syndrome associated with impaired water excretion and low levels of sodium (SIADH).
- Loss of consciousness due to severe decrease in blood sugar levels (hypoglycaemic coma). See section 2.

Very rare cases of long lasting (up to months or years) or permanent adverse drug reactions, such as tendon inflammations, tendon rupture, joint pain, pain in the limbs, difficulty in walking, abnormal sensations such as pins and needles, tingling, tickling, burning, numbness or pain (neuropathy), fatigue, memory and concentration impairment, mental health effects (which may include sleep disorders, anxiety, panic attacks, depression and suicidal ideation), as well as impairment of hearing, vision, and taste and smell have been associated with administration of quinolone and fluoroquinolone antibiotics, in some cases irrespective of pre-existing risk factors.

Cases of an enlargement and weakening of the aortic wall or a tear in the aortic wall (aneurysms and dissections), which may rupture and may be fatal, and of leaking heart valves have been reported in patients receiving fluoroquinolones. See also section 2.

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, Website: www.hpra.ie.

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

5. How to store Cifloxager

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the the blister or 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

- The active substance is ciprofloxacin. Each film-coated tablet contains 250 mg or 500 mg of ciprofloxacin (as ciprofloxacin hydrochloride).
- 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, 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.

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