

Cifox 750 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 any 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 Cifox is and what it is used for
2. What you need to know before you take Cifox
3. How to take Cifox
4. Possible side effects
5. How to store Cifox
6. Contents of the pack and other information.

1 What Cifox is and what it is used for

Cifox 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

Cifox 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 Cifox.

Children and adolescents

Cifox 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.

Cifox 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 Cifox

Do not take Cifox if you are

- allergic to ciprofloxacin, to other quinolone drugs or any of the other ingredients of this medicine (listed in section 6)
- taking tizanidine (see Section 2: Other medicines and Cifox).

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.

You should not take fluoroquinolone/quinolone antibacterial medicines, including Cifox 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.

Warnings and precautions

Talk to your doctor before taking Cifox if you:

- have ever had kidney problems because your treatment may need to be adjusted
- suffer from epilepsy or other neurological conditions
- have a history of tendon problems during previous treatment with antibiotics such as Cifox
- are diabetic because you may experience a risk of hypoglycaemia with ciprofloxacin
- have myasthenia gravis (a type of muscle weakness) because symptoms can be exacerbated
- have 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 levels 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 Cifox).
- 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 been diagnosed with an enlargement or "bulge" of a large vessel (aortic aneurysm or large vessel peripheral aneurysm)
- have experienced a previous episode of aortic dissection (a tear in the aorta wall)
- 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]).

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.

While taking Cifox

Tell your doctor immediately, if any of the following occurs **during treatment with Cifox**.

Your doctor will decide whether treatment with Cifox 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 experience dizziness on standing.

If this happens, stop taking Cifox and contact your doctor 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 Cifox therapy. At the first sign of pain or inflammation of a tendon (for example in your ankle, wrist, elbow, shoulder or knee), stop taking Cifox, 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 Cifox and contact your doctor immediately.
- 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.
- You may experience **psychiatric reactions** the first time you take ciprofloxacin. If you suffer from **depression** or **psychosis**, your symptoms may become worse under treatment with Cifox. In rare cases, depression or psychosis can progress to thoughts of suicide, suicide attempts, or completed suicide. If this happens, stop taking Cifox and 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 Cifox and inform your doctor immediately in order to prevent the development of potentially irreversible condition.
- Hypoglycaemia has been reported most often in diabetic patients, predominantly in elderly population. If this happens, contact your doctor immediately.
- **Diarrhoea** may develop while you are on antibiotics, including Cifox or even several weeks after you have stopped taking them. If it becomes severe or persistent or you notice that your stools contain blood or mucus, stop taking this medicine 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 Cifox 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.
- Ciprofloxacin 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 Cifox and contact your doctor immediately.
- Ciprofloxacin 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.
- Your skin becomes more sensitive to **sunlight or ultraviolet (UV) light** when taking ciprofloxacin. 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.
- **Prolonged, disabling and potentially irreversible serious side effects**
Fluoroquinolone/quinolone antibacterial medicines, including Cifox, 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 Cifox, 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.

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Other medicines and Cifox

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

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

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

Tell your doctor if you are taking:

- vitamin K antagonists (e.g. warfarin, acenocoumarol, phenprocoumon or fludione or other oral anti-coagulants (to thin the blood))
- probenecid (for gout)
- methotrexate (for certain types of cancer, psoriasis, rheumatoid arthritis)
- theophylline (for breathing problems)
- tizanidine (for muscle spasticity in multiple sclerosis)
- olanzapine (an antipsychotic)
- clozapine (an antipsychotic)
- ropinirole (for Parkinson's disease)
- phenytoin (for epilepsy)
- metoclopramide (for nausea and vomiting)
- ciclosporin (for skin conditions, rheumatoid arthritis and in organ transplantation)
- 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.

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

- pentoxifylline (for circulatory disorders)
- caffeine
- duloxetine (for depression, diabetic nerve damage or incontinence)
- lidocaine (for heart conditions or anesthetic use)
- sildenafil (for erectile problems)
- agomelatine
- zolpidem.

Some medicines may reduce the effect of Cifox tablets. Tell your doctor if you take or wish to take

- antacids
- omeprazole
- mineral supplements
- sucralfate
- a polymeric phosphate binder (e.g. sevelamer or lanthanum carbonate)
- medicines or supplements containing calcium, magnesium, aluminium or iron.

If these preparations are essential, take Cifox about two hours before or no sooner than four hours after them.

Cifox with food and drink

Unless you take Cifox during meals, do not eat or drink any dairy products (such as milk or yoghurt) or drinks with added calcium when you take the tablets, as they may affect the absorption of the active substance.

Pregnancy and breast-feeding

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 any medicine.

It is preferable to avoid the use of Cifox during pregnancy.

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

Driving and using machines

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

Cifox contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially "sodium free".

3 How to take Cifox

Your doctor will explain to you exactly how much Cifox 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.

Tell your doctor if you suffer from kidney problems because your dose may need to be adjusted.

Treatment usually lasts between 5 and 21 days, but may be longer for severe infections. Take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure how many tablets to take and how to take Cifox.

a. Swallow the tablets with plenty of fluid. Do not chew the tablets because they do not taste nice.

b. Try to take the tablets at around the same time every day

c. You can take the tablets at mealtimes or between meals. Any calcium you take as part of a meal will not seriously affect the uptake. However, do not take Cifox with dairy products such as milk or yoghurt or with fortified fruit juices (e.g. calcium-fortified orange juice).

Remember to drink plenty of fluids while you are taking Cifox.

If you take more Cifox than you should

- If you take more than the prescribed dose, get medical help immediately. If possible take your tablets or the box with you to show the doctor.

If you forget to take Cifox

Take the normal dose as soon as possible and then continue as prescribed. However, if it is almost time for your next dose, do not take the missed dose and continue as usual. Do not take a double dose to make up for the forgotten dose. Be sure to complete your course of treatment.

If you stop taking Cifox

It is important that you **finish the course of treatment**, even if you begin to feel better after a few days. 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.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Common: may affect up to 1 in 10 people

- nausea, diarrhoea
- joint pain in children.

Uncommon: may affect up to 1 in 100 people

- fungal superinfections
- a high concentration of eosinophils, a type of white blood cell
- decreased appetite
- hyperactivity or agitation
- headache, dizziness, sleeping problems, taste disorders
- vomiting, abdominal pain, digestive problems such as stomach upset (indigestion/heartburn), wind
- increased amounts of certain substances in the blood (transaminases and/or bilirubin)
- rash, itching, hives
- joint pain in adults
- poor kidney function
- pains in your muscles and bones, feeling unwell (asthenia), fever
- increase in blood alkaline phosphatase (a certain substance in the blood).

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

- inflammation of the bowel (colitis) linked to antibiotic use (can be fatal in rare cases) (see Section 2: Warning and Precautions)
- changes to the blood count (leukopenia, leukocytosis, neutropenia, anaemia), increased or decreased amounts of a blood clotting factor (thrombocytes)
- allergic reaction, swelling (oedema), rapid swelling of the skin and mucous membranes (angio-oedema)
- increased blood sugar (hyperglycaemia)
- decreased blood sugar (hypoglycaemia) (see section 2: Warnings and Precautions)
- confusion, disorientation, anxiety reaction, strange dreams, depression (potentially leading to thoughts of suicide, suicide attempts, or completed suicide), or hallucinations
- pins and needles, unusual sensitivity to stimuli of the senses, decreased skin sensitivity, tremors, seizures (see Section 2: Warnings and Precautions) or giddiness
- eyesight problems including double vision
- expansion of the blood vessels (vasodilation), low blood pressure, or fainting
- tinnitus, loss of hearing, impaired hearing
- rapid heartbeat (tachycardia)
- shortness of breath including asthmatic symptoms
- liver disorders, jaundice (cholestatic icterus) or hepatitis
- sensitivity to light (see Section 2: Warnings and

Precautions)

- muscle pain, inflammation of the joints, increased muscle tone, cramping
- kidney failure, blood or crystals in the urine (see Section 2: Warnings and Precautions), urinary tract inflammation
- fluid retention or excessive sweating
- 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 cell (agranulocytosis), a drop in the number of red and white blood cells and platelets (pancytopenia), which may be fatal, bone-marrow depression which may also be fatal (see Section 2: Warnings and Precautions)
- severe allergic reaction (anaphylactic reaction, anaphylactic shock - serum sickness which can be fatal) (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, disturbed coordination, unsteady walk (gait disturbance), disorder of sense of smell (olfactory disorders), pressure on the brain (intracranial pressure and pseudotumor cerebri)
- visual colour distortions
- inflammation of the wall of the blood vessel (vasculitis)
- pancreatitis
- death of liver cells (liver necrosis) very rarely leading to life-threatening liver failure
- small, pin-point bleeding under the skin (petechiae)
- various skin eruptions or rashes (e.g. the potentially fatal Stevens-Johnson syndrome or toxic epidermal necrolysis)
- muscle weakness, tendon inflammation, tendon rupture, especially of the large tendon at the back of the ankle (Achilles tendon), worsening of the symptoms of myasthenia gravis (see Section 2: Take special care with Cifox).

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
- 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)
- pustular rash
- influence on blood clotting (in patients taking vitamin K antagonists)
- feeling highly excited (mania) or feeling great optimism and overactivity (hypomania)
- serious hypersensitivity reaction called DRESS (Drug Reaction with Eosinophilia and Systemic Symptoms)
- 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), depression, fatigue, sleep disorders, memory impairment, 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC 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 Cifox

Do not store above 25°C.

Store in the original package in order to protect from light.

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 carton and blister after EXP. The expiry date refers to the last day of that month.

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 to protect the environment.

6 Contents of the pack and other information

What Cifox contains

- The active substance is ciprofloxacin (as hydrochloride). Each film-coated tablet contains 750 mg ciprofloxacin (as hydrochloride).
- The other ingredients are:
Tablet core: croscarmellose sodium, sodium starch glycolate (type A), microcrystalline cellulose, magnesium stearate, povidone, colloidal anhydrous silica, stearic acid.
Film-coating: hypromellose, macrogol 6000, titanium dioxide (E171) and talc.

What Cifox looks like and contents of the pack

Cifox 750 mg film-coated tablets are white, oblong, scored on both sides, embossed with 'cip 750'.

Cifox 750 mg film-coated tablets are packed into PVC/aluminium or PP/Aluminium blisters and are available in pack sizes of 10 film-coated tablets.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder:

Rowex Ltd, Bantry, Co Cork, Ireland

Manufacturers:

Salutas Pharma GmbH, Otto-von-Guericke Allee 1, 39179 Barleben, Germany
Rowa Pharmaceuticals Ltd., Bantry, Co Cork, Ireland
Sandoz S.R.L., 7A Livezeni Street, Targu Mures, Romania

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Advice/medical education

Antibiotics are used to cure bacterial infections. They are ineffective against viral infections. If your doctor has prescribed antibiotics, you need them precisely for your current illness. Despite antibiotics, some bacteria may survive or grow. This phenomenon is called resistance: some antibiotic treatments become ineffective. Misuse of antibiotics increases resistance. You may even help bacteria become resistant and therefore delay your cure or decrease antibiotic efficacy if you do not respect appropriate:

- dosage
- schedules
- duration of treatment.

Consequently, to preserve the efficacy of this drug:

- 1 - Use antibiotics only when prescribed.
- 2 - Strictly follow the prescription.
- 3 - Do not re-use an antibiotic without medical prescription, even if you want to treat a similar illness.
- 4 - Never give your antibiotic to another person; maybe it is not adapted to her/his illness.
- 5 - After completion of treatment, return all unused drugs to your chemist's shop to ensure they will be disposed of correctly.