

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 more 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.



△ CIPROZAD film-coated tablets 250 mg  
△ CIPROZAD film-coated tablets 500 mg  
Ciprofloxacin

### What is in this leaflet

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

### 1. What **Ciprozad** is and what it is used for

**Ciprozad** 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

**Ciprozad** is used in adults to treat the following bacterial infections:

- respiratory tract infections
- long lasting or recurring ear or sinus infections
- urinary tract infections
- testis infection
- genital organ infections in women
- gastro-intestinal tract infections and intra-abdominal infections
- skin and soft tissue infections
- bone and joint infections
- to treat infections in patients with a very low white blood cell count (neutropenia)
- to prevent infections in patients with a very low white blood cell count (neutropenia)
- to prevent infections due to the bacterium *Neisseria meningitidis*
- anthrax inhalation exposure

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 **Ciprozad**.

#### Children and adolescents

**Ciprozad** 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 **Ciprozad** may also be used to treat other specific severe infections in children and adolescents when your doctor considered this necessary.

### 2. What you need to know before you take **Ciprozad**

#### Do not take **Ciprozad**:

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

#### Warnings and precautions

Talk to your doctor or pharmacist before taking **Ciprozad** 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 **Ciprozad**
- have myasthenia gravis (a type of muscle weakness)
- have a history of abnormal heart rhythms (arrhythmias)

#### While taking **Ciprozad**

Tell your doctor immediately, if any of the following occurs while taking **Ciprozad**. Your doctor will decide whether treatment with **Ciprozad** 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 **Ciprozad** and contact your doctor immediately.
- Pain and swelling in the joints and tendonitis 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 **Ciprozad** 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 **Ciprozad** and contact your doctor immediately.
- You may experience psychiatric reactions the first time you take **Ciprozad**. If you suffer from depression or psychosis, your symptoms may become worse under treatment with **Ciprozad**. If this happens,

stop taking **Ciprozad** 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 **Ciprozad** and contact your doctor immediately.
- Diarrhoea may develop while you are taking antibiotics, including **Ciprozad**, 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 **Ciprozad** 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 **Ciprozad** if you have to provide a blood or urine sample.
- **Ciprozad** 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 **Ciprozad** and contact your doctor immediately.
- **Ciprozad** 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 anemia with **Ciprozad**.
- Your skin becomes more sensitive to sunlight or ultraviolet (UV) light when taking **Ciprozad**. Avoid exposure to strong sunlight, or artificial UV light such as sunbeds.

#### Other medicines and **Ciprozad**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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

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

Tell your doctor if you are taking:

- warfarin or other oral anti-coagulants (to thin the blood)
- theophylline (for breathing problems)
- phenytoin (for epilepsy)
- probenecid (for gout)
- ropinirole (for Parkinson's disease)
- methotrexate (for certain types of cancer, psoriasis, rheumatoid arthritis)
- tizanidine (for muscle spasticity in multiple sclerosis)
- metoclopramide (for nausea and vomiting)
- cyclosporine (for skin conditions, rheumatoid arthritis, and organ transplants)
- olanzapine (an antipsychotic)
- clozapine (an antipsychotic)
- other medicines that affect your heart rate (quinidine, hydroquinidine, disopramide, amiodarone, sotalol, dofetilide, ibutilide), tricyclic antidepressants, some antimicrobials (macrolids), some antipsychotics.

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

- pentoxifylline (for circulatory disorders)
- caffeine
- duloxetine (for depression, diabetes caused nerves damage, incontinence)
- lidocaine (for heart conditions, anesthetic application)
- sildenafil (for erectile dysfunction)

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

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

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

#### **Ciprozad** with food and drink

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. Food with a small amount of calcium does not significantly affect the absorption of ciprofloxacin.

### **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 this medicine. It is preferable to avoid the use of **Ciprozad** during pregnancy.

Tell your doctor if you are pregnant or planning to become pregnant. Do not take **Ciprozad** during breast feeding because ciprofloxacin is excreted in breast milk and can be harmful for your child.

### **Driving and using machines**

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

### **3. How to take Ciprozad**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Tell your doctor if you suffer from kidney problems because your dose may need to be adjusted. The treatment usually lasts from 5 to 21 days, but may take longer or severe infections. Take the tablets exactly as your doctor has told you. Ask your doctor or pharmacist if you are not sure how many tablets to take and how to take **Ciprozad**.

Remember to drink plenty of fluids while you are taking **Ciprozad**.

### **If you take more Ciprozad 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 Ciprozad**

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 a forgotten dose. Be sure to complete your course of treatment.

### **If you stop taking Ciprozad**

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.

**Common side effects** (may affect 1-10 in 100 people):

- nausea, diarrhea
- joint pains in children

**Uncommon side effects** (may affect 1-10 in 1000 people):

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

**Rare side effects** (may affect 1-10 in 10,000 people):

- inflammation of the bowel (colitis) linked to antibiotic use (can be fatal in very rare cases) (see Section 2: Warnings 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), or rapid swelling of the skin and mucous membranes (angio-oedema)
- increased blood sugar (hyperglycaemia)
- confusion, disorientation, anxiety reactions, strange dreams, depression 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
- tinnitus, loss of hearing, impaired hearing
- rapid heartbeat (tachycardia)
- expansion of blood vessels (vasodilation), low blood pressure, or fainting
- shortness of breath, including asthmatic symptoms
- liver disorders, jaundice (cholestatic icterus), or hepatitis
- sensitivity to sun and UV light (see Section 2: Warnings and precautions)
- muscle pain, inflammation of the joints, increased muscle tone, or cramp
- kidney failure, blood or crystals in the urine (see Section 2: Warnings and precautions), urinary tract inflammation
- fluid retention or excessive sweating
- abnormal levels of a clotting factor (prothrombin) or increased levels of the enzyme amylase

**Very rare side effects** (may affect less than 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); 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 (see Section 2: Warnings and precautions)
- severe allergic reactions (anaphylactic reaction or anaphylactic shock, which can be fatal - serum sickness) (see Section 2: Warnings and precautions)
- mental disturbances (psychotic reactions) (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)
- visual colour distortions
- inflammation of the wall of the blood vessels (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 (for example, 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) (see Section 2: Warnings and precautions) worsening of the symptoms of myasthenia gravis (see Section 2: Warnings and precautions)

**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
- severe skin rash
- severe cardiac rhythm abnormalities, irregular heart beat (Torsades de pointes)
- effect on blood clotting (in patients who take vitamin K antagonists)

### **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.

### **5. How to store Ciprozad**

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

Do not use this medicine after the expiry date stated on the blister and on the carton. The expiry date refers to the last day of that month. Do not store above 30°C.

### **6. Contents of the pack and other information**

**CIPROZAD 250 mg:** 1 tablet contains 250 mg ciprofloxacin, as ciprofloxacin hydrochloride, as active substance.

**CIPROZAD 500 mg:** 1 tablet contains 500 mg ciprofloxacin, as ciprofloxacin hydrochloride, as active substance.

The other ingredients are: microcrystalline cellulose, corn starch, povidone, crospovidone, talc, silicon colloidal anhydride, magnesium stearate.

Film: Opadry II white, purified water.

### **What Ciprozad looks like and contents of the pack**

Box of 10 (1x10) film-coated tablets of 250 mg ciprofloxacin in blister packs.

Box of 10 (1x10) film-coated tablets of 500 mg ciprofloxacin in blister packs.

Box of 14 (2x7) film-coated tablets of 500 mg ciprofloxacin in blister packs.

### **Marketing Authorisation Holder and Manufacturer**

ZADA Pharmaceuticals Ltd.

Donji Bistarac bb

75300 Lukavac, Bosnia and Herzegovina

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### **Data of first authorisation / renewal of the authorisation in Bosnia and Herzegovina:**

Δ CIPROZAD film-coated tablets, 10X250 mg:

**Date:** 03.11.2015.

**Number:** 04-07.3-2-5044/15

Δ CIPROZAD film-coated tablets, 10X500 mg:

**Date:** 03.11.2015.

**Number:** 04-07.3-2-5045/15

Δ CIPROZAD film-coated tablets, 14X500 mg:

**Date:** 03.11.2015.

**Number:** 04-07.3-2-5046/15