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Due to regulatory changes, the content of the following Patient Information Leaflet may vary from the one found in your medicine pack. Please compare the 'Leaflet prepared/revised date' towards the end of the leaflet to establish if there have been any changes.

If you have any doubts or queries about your medication, please contact your doctor or pharmacist.



## PACKAGE LEAFLET: INFORMATION FOR THE USER

### Ciproxin 500 mg film-coated tablets

Ciprofloxacin

**Read all of this leaflet carefully before you start taking this medicine.**

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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.

#### **In this leaflet:**

1. What Ciproxin is and what it is used for
2. Before you take Ciproxin
3. How to take Ciproxin
4. Possible side effects
5. How to store Ciproxin
6. Further information

### **1. WHAT CIPROXIN IS AND WHAT IT IS USED FOR**

Ciproxin 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

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

- respiratory tract infections
- long lasting or recurring ear or sinus infections
- urinary tract infections
- infections of the testicles
- 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 Ciproxin.

### Children and adolescents

Ciproxin 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

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

## **2. BEFORE YOU TAKE CIPROXIN**

### **Do not take Ciproxin if you are:**

- allergic (hypersensitive) to the active substance, to other quinolone drugs or to any of the other ingredients of Ciproxin (see section 6)
- taking tizanidine (see Section 2: Taking other medicines)

### **Take special care with Ciproxin**

#### **Before taking Ciproxin**

Tell your doctor 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 Ciproxin
- have myasthenia gravis (a type of muscle weakness)
- have a history of abnormal heart rhythms (arrhythmias)

#### **While taking Ciproxin**

Tell your doctor immediately, if any of the following occurs **while taking Ciproxin**. Your doctor will decide whether treatment with Ciproxin 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 Ciproxin 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 Ciproxin 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 Ciproxin and contact your doctor immediately.
- You may experience **psychiatric reactions** the first time you take Ciproxin. If you suffer from **depression** or **psychosis**, your symptoms may become worse under treatment with Ciproxin. If this happens, stop taking Ciproxin 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 Ciproxin and contact your doctor immediately.
- **Diarrhoea** may develop while you are taking antibiotics, including Ciproxin, 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 Ciproxin 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 Ciproxin if you have to provide a **blood or urine sample**.
- Ciproxin 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 Ciproxin and contact your doctor immediately.
- Ciproxin 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 ciprofloxacin.
- Your skin becomes more **sensitive to sunlight or ultraviolet (UV) light** when taking Ciproxin. Avoid exposure to strong sunlight, or artificial UV light such as sunbeds.

### **Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including any that you obtained without a prescription.

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

The following medicines are known to interact with Ciproxin in your body. Taking Ciproxin 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)
- probenecid (for gout)
- methotrexate (for certain types of cancer, psoriasis, rheumatoid arthritis)
- theophylline (for breathing problems)
- tizanidine (for muscle spasticity in multiple sclerosis)
- clozapine (an antipsychotic)
- ropinirole (for Parkinson's disease)
- phenytoin (for epilepsy)

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

- pentoxifylline (for circulatory disorders)
- caffeine

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

- antacids
- 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 Ciproxin about two hours before or no sooner than four hours after them.

**Taking Ciproxin with food and drink**

Unless you take Ciproxin 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**

It is preferable to avoid the use of Ciproxin during pregnancy. Tell your doctor if you are planning to get pregnant.

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

**Driving and using machines**

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

**3. HOW TO TAKE CIPROXIN**

Your doctor will explain to you exactly how much Ciproxin 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.

The treatment usually lasts from 5 to 21 days, but may take longer for 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 Ciproxin.

- a. Swallow the tablets with plenty of fluid. Do not chew the tablets because they do not taste nice.
- b. Do 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 uptake. However, **do not** take Ciproxin tablets 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 Ciproxin.

### **If you take more Ciproxin 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 Ciproxin**

- 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 Ciproxin**

- 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 more questions about the use of this product, ask your doctor or pharmacist.

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, Ciproxin 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, tell your doctor or pharmacist.

**Common side effects** (between 1 and 10 in every 100 people are likely to get these):

- nausea, diarrhoea
- joint pains in children

**Uncommon side effects** (between 1 and 10 in every 1,000 people are likely to get these):

- 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** (between 1 and 10 in every 10,000 people are likely to get these):

- inflammation of the bowel (colitis) linked to antibiotic use (can be fatal in very rare cases) (see Section 2: Take special care with Ciproxin)
- 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: Take special care with Ciproxin), 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 light (see Section 2: Take special care with Ciproxin)
- muscle pain, inflammation of the joints, increased muscle tone, or cramp
- kidney failure, blood or crystals in the urine (see Section 2: Take special care with Ciproxin), 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** (less than 1 in every 10,000 people are likely to get these):

- 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: Take special care with Ciproxin)
- severe allergic reactions (anaphylactic reaction or anaphylactic shock, which can be fatal - serum sickness) (see Section 2: Take special care with Ciproxin)
- mental disturbances (psychotic reactions) (see Section 2: Take special care with Ciproxin)
- 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: Take special care with Ciproxin); worsening of the symptoms of myasthenia gravis (see Section 2: Take special care with Ciproxin)

**Frequency not known** (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 cardiac rhythm abnormalities, irregular heart beat (Torsades de Pointes)

## 5. HOW TO STORE CIPROXIN

Store in the original pack. There are no special storage requirements, but it is best to keep Ciproxin in a cool, dry place.

**Keep out of the reach and sight of children.**

Do not use Ciproxin after the expiry date, which is stated on the blister or carton after “EXP”: The expiry date refers to the last day of the month concerned.

Medicines should not be disposed of down the drain or with household rubbish. Ask your pharmacist how to dispose of any medicines no longer required. These measures will help to protect the environment.

## 6. FURTHER INFORMATION

### What Ciproxin contains

Ciproxin 500 mg film-coated tablets contain the active ingredient, ciprofloxacin.

Ciproxin 500 mg film-coated tablets also contain microcrystalline cellulose, maize starch, crospovidone, colloidal silicon dioxide, magnesium stearate and purified water. The tablet film-coat consists of a mixture of hypromellose, Macrogol 4000, titanium dioxide and purified water.

### What Ciproxin looks like and contents of the pack

Film-coated tablet

The tablets are available in blister packs containing 10, 20 or 100 tablets.

### Marketing Authorisation Holder and Manufacturer

|                                |   |
|--------------------------------|---|
| Marketing authorisation holder | Bayer plc<br>Bayer Schering Pharma<br>Bayer House<br>Strawberry Hill<br>Newbury<br>Berkshire RG14 1JA |
|--------------------------------|---|

|               |                          |
|---------------|--------------------------|
| Manufacturer: | Bayer Schering Pharma AG |
|---------------|--------------------------|

**This medicinal product is authorised in the Member States of the EEA under the following names:**

|                 |           |
|-----------------|-----------|
| Austria:        | Ciproxin  |
| Belgium:        | Ciproxine |
| Bulgaria:       | Ciprobay  |
| Cyprus:         | Ciproxin  |
| Czech Republic: | Ciprobay  |
| Denmark:        | Ciproxin  |

|                  |                                 |
|------------------|---------------------------------|
| Estonia:         | Ciproxin                        |
| Finland:         | Ciproxin                        |
| France:          | Ciflox; Uniflox                 |
| Germany:         | Ciprobay; Ciprofloxacin ANTIBAC |
| Greece:          | Ciproxin                        |
| Hungary:         | Ciprobay                        |
| Iceland:         | Ciproxin                        |
| Ireland:         | Ciproxin                        |
| Italy:           | Ciflox; Ciproxin                |
| Luxembourg:      | Ciproxine                       |
| Malta:           | Ciproxin                        |
| Netherlands:     | Ciproxin                        |
| Norway:          | Ciproxin                        |
| Poland:          | Ciprobay                        |
| Portugal:        | Ciproxina                       |
| Romania:         | Ciprobay                        |
| Slovak Republic: | Ciprobay                        |
| Slovenia:        | Ciprobay                        |
| Spain:           | Baycip                          |
| Sweden:          | Ciproxin                        |
| United Kingdom:  | Ciproxin                        |

**This leaflet was last approved in November 2008**

#### **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:

- dosages
- 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.