

PACKAGE LEAFLET: INFORMATION FOR THE USER

Emicipro 250mg film-coated tablets

Emicipro 500mg film-coated tablets

Emicipro 750mg 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 Emicipro is and what it is used for | 4. Possible side effects |
| 2. Before you take Emicipro                 | 5. How to store Emicipro |
| 3. How to take Emicipro                     | 6. Further information   |

1. WHAT EMICIPRO IS AND WHAT IT IS USED FOR

Emicipro 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

Emicipro 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 Emicipro.

Children and adolescents

Emicipro 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.

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

2. BEFORE YOU TAKE EMICIPRO

Do not take Emicipro If you are:

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

Take special care with Emicipro

Before taking Emicipro

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 Ciprofloxacin
- have myasthenia gravis (a type of muscle weakness)
- have heart problems. Caution should be taken when using Ciprofloxacin, 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: Taking other medicines). 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 Emicipro

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

- **Severe, sudden allergic reaction** (an anaphylactic reaction/shock, angioedema). 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 Emicipro 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. Inflammation and ruptures of tendons may occur even within the first 48 hours of treatment or up to several months after discontinuation of Emicipro therapy. At the first sign of any pain or inflammation stop taking Emicipro 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 Emicipro and contact your doctor immediately.

- You may experience **psychiatric reactions** the first time you take Emicipro. If you suffer from **depression** or **psychosis**, your symptoms may become worse under treatment with Emicipro. In rare cases, depression or psychosis can progress to thoughts of suicide, suicide attempts, or completed suicide. If this happens, stop taking Emicipro 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 Emicipro and contact your doctor immediately.

- **Diarrhoea** may develop while you are taking antibiotics, including Emicipro, 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 Emicipro 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 Emicipro 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.
- Emicipro 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 Emicipro and contact your doctor immediately.

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

The following medicines are known to interact with Emicipro in your body. Taking Emicipro 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:

- Vitamin K antagonists (e.g. 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)
- olanzapine (an antipsychotic)
- cizolapine (an antipsychotic)
- ropinirole (for Parkinson's disease)
- phenytoin (for epilepsy)
- mexiletine (used to treat abnormal heart beats).
- metoclopramide (for nausea and vomiting)
- cyclosporin (for skin conditions, rheumatoid arthritis and in organ transplantation)
- glibenclamide (for diabetes)
- 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.

Emicipro 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 (e.g. for erectile dysfunction)

Some medicines **reduce** the effect of Emicipro. 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 (e.g. didanosine tablets (an antiviral drug used to treat HIV). If these preparations are essential, take Emicipro about two hours before or no sooner than four hours after them.

Taking Emicipro with food and drink

Unless you take Emicipro 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 Emicipro during pregnancy. Tell your doctor if you are planning to get pregnant. Do not take Emicipro during breast feeding because ciprofloxacin is excreted in breast milk and can be harmful for your child.

Driving and using machines

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

3. HOW TO TAKE EMICIPRO

**Always take ciprofloxacin tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.**

Take the tablets exactly as your doctor has told you. The tablets should **always** be taken with plenty of water, as this will help to prevent the formation of tiny crystals in your urine (crystalluria).

You can take the tablets at meal times or between meals. Any calcium you take as a part of a meal will not seriously affect uptake. However, **do not take ciprofloxacin tablets with dairy products** such as milk or yogurt or with fortified fruit juices (eg. Calcium-fortified orange juice). Tell your doctor if you suffer from kidney problems because your dose may need to be adjusted. Your dose will be dependent on the type and severity of your infection, your age, weight and kidney function. Your doctor will choose the best dose for you.

Adults

The usual adult dose is between 100 – 750mg twice daily. In Respiratory infections the usual dose is 500mg-750mg twice daily. In infections of the bladder and kidneys, the usual dose is 250 - 500mg twice daily.

In gonorrhoea, the usual dose is 250 - 500mg as a single dose. In gastro-intestinal infections, the usual dose is 500 mg twice daily. In intra-abdominal infections, skin and soft tissue infections, bone and joint infections, and in neutropenic patients the usual dose is 500-750mg twice daily. In infections due to Bacterium *Neisseria meningitidis* the usual dose is 500mg as a single dose. Inhalation anthrax exposure the usual dose is 500mg twice daily.

Elderly Patients

Your doctor will decide what dose to give you. This may be lower than the usual adult dose depending on the severity of your infection and your kidney function.

Kidney/Liver problems

Your doctor will decide what dose to give you depending on your kidney and liver function. Special dosing instructions are needed if you are on haemodialysis or having CAPD (continuous ambulatory peritoneal dialysis).

Children and adolescents

The use of Ciprofloxacin Tablets is not generally recommended in children. However, in some cases treatment with these tablets is of benefit and your doctor may decide to treat your child with this drug particularly for the below mentioned infections. Cystic fibrosis the usual dose is 20mg/kg body weight twice daily with a maximum daily dose of 750 mg. Complicated urinary tract infections and pyelonephritis the usual dose is 10 to 20 mg/kg body weight twice daily with a maximum of 750mg per dose. Inhalation anthrax exposure the usual dose is 10 to 15 mg/kg body weight twice daily with a maximum of 500mg per dose. Other severe infections the usual dose is 20mg /kg body weight twice daily with a maximum of 750mg per dose.

It is very important that you follow your doctor's instructions as to how many Ciprofloxacin Tablets to take, how often to take them and for how long you should continue to take your tablets. The normal duration of treatment is between 5 to 21 days (although this may be longer), depending on the type and severity of infection.

If you take more Emicipro 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 Emicipro

- 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 Emicipro

- 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, Emicipro can cause side effects, although not everybody gets them.

About 5 – 14% of patients have side-effects and the most common side-effects involve the gut and the nervous system.

If any of the following symptoms occur soon after taking your tablets, **stop taking the tablets and tell your doctor immediately**. This kind of reaction is rare and may mean you are suffering from an allergic reaction to the tablets:

- Rash, itching, a lumpy skin rash ('hives'), fever, small red spots on the body, increased sensitivity to sunlight or very rarely severe skin reactions such as large fluid filled blisters, peeling, sores and ulceration. Ulceration can also occur in the mouth and throat, around the anus and genital region and on the surface of the eyes
- Sudden wheeziness or tightness of the chest
- Swelling of the eyelids, face, lips or blood vessels in the skin
- Sickness and headache.

You should also tell your doctor **immediately** and **stop** taking your tablets if you notice:

- Pain or inflammation in the tendons. This effect occurs in isolated cases. If these symptoms are experienced you should stop taking your tablet, rest the affected limb and consult your doctor **immediately**.
- Severe diarrhoea with bleeding or mucus. This effect occurs in less than one in a thousand but more than one in ten thousand people.
- A feeling that you want to physically harm yourself. This only occurs in isolated cases.

**Other possible side-effects, which may occur, are listed below:**

**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
- 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 Emicipro)
  - 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 (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: Take special care with Emicipro), or giddiness
  - eyesight problems including double vision
  - 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 Emicipro)
  - 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 Emicipro), urinary tract inflammation
  - fluid retention or excessive sweating
  - increased levels of the enzyme amylose
- 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 Emicipro)
  - severe allergic reactions (anaphylactic reaction or anaphylactic shock, which can be fatal - serum sickness) (see Section 2: Take special care with Emicipro)
  - mental disturbances (psychotic reactions potentially leading to thoughts of suicide, suicide attempts, or completed suicide) (see Section 2: Take special care with Emicipro)
  - 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
  - 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 Emicipro); worsening of the symptoms of myasthenia gravis (see Section 2: Take special care with Emicipro)
  - **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
  - 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 treated with Vitamin K antagonists)

5. HOW TO STORE EMICIPRO

Keep out of the reach and sight of children. Store below 25° C in a dry place. Protect from light.

Do not use Emicipro after the expiry date, which is stated on the blister and carton after "EXP". The expiry date refers to the last day of that month. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of any medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Emicipro contains

The active substance is ciprofloxacin.

**Emicipro 250 mg film-coated tablets:** The active substance in each film-coated tablet is Ciprofloxacin Hydrochloride equivalent to 250mg Ciprofloxacin.

**Emicipro 500 mg film-coated tablets:** The active substance in each film-coated tablet is Ciprofloxacin Hydrochloride equivalent to 500mg Ciprofloxacin.

**Emicipro 750 mg film-coated tablets:** The active substance in each film coated tablet is Ciprofloxacin Hydrochloride equivalent to 750mg Ciprofloxacin.

The other ingredients are:

Tablet core: Maize Starch, Microcrystalline cellulose, Sodium lauryl Sulfate, Magnesium Stearate, Purified Talc, Colloidal Anhydrous Silica, Sodium Starch Glycolate and Croscopdone. Film-coat: Hypromellose, Polyethyleneglycol, Titanium Dioxide, Simethicone emulsion.

Presentation:

Emicipro 250 mg film-coated tablets in packs of 10 tablets (1 blister, each has 10 film-coated tablets).

Emicipro 500 mg film-coated tablets in packs of 10 tablets (1 blister, each has 10 film-coated tablets).

Emicipro 750 mg film-coated tablets in packs of 10 tablets (1 blister, each has 10 film-coated tablets).

Marketing Authorization Holder and Manufacturer:

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How can you obtain more information about Emicipro?

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

To report any side effects:

Please contact the relevant competent authority.

THIS IS A MEDICAMENT

- A Medicament is a product, which affects your health, and its consumption, contrary to instruction, is dangerous for you.

- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.

- The doctor and the pharmacist are experts in medicine, its benefits and risks.

- Do not, by yourself, interrupt the period of treatment prescribed for you.

- Do not repeat the same prescription without consulting your doctor.

KEEP MEDICAMENTS OUT OF THE REACH OF CHILDREN

Council of Arab Health Ministers

Union of Arab Pharmacist

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