1.5.3 Patient Information Leaflet (PIL)

Package leaflet: Information for the patient

FLUOXINE 500, film-coated tablet
FLUOXINE 750, film-coated tablet
Ciprofloxacin hydrochloride

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, please ask your doctor or your pharmacist
. This medicine has been prescribed for you personally 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 in this leaflet:

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

1. WHAT FLUOXINE IS AND WHAT IT IS USED FOR

Fluoxine 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

Fluoxine 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 meningitides
- 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 Fluoxine.

Children and adolescents

Fluoxine 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

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

2. BEFORE YOU TAKE FLUOXINE

Do not take Fluoxine if you are:

- allergic (hypersensitive) to ciprofloxacin, to other quinolone drugs or to any of the other ingredients of Fluoxine (see section 6)
- taking tizanidine (see Section 2: Other medicines and Fluoxine)

Warnings and precautions

Talk to your doctor before taking Fluoxine:

- if you have ever had kidney problems because your treatment may need to be adjusted
- if you suffer from epilepsy or other neurological conditions
- if you have a history of tendon problems during previous treatment with antibiotics such as Fluoxine
- if you have myasthenia gravis (a type of muscle weakness) because symptoms can be exacerbated
- if you have heart problems.
  Caution should be taken when using ciprofloxacin, if you were born with or have family history of prolonged QT interval (see 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 results in abnormal ECG changes (see section 2: Other medicines and Fluoxine).

While taking Fluoxine:

Tell your doctor immediately, if any of the following occurs while taking Fluoxine. Your doctor will decide whether treatment with Fluoxine 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 Fluoxine 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 Fluoxine 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 Fluoxine and contact your doctor immediately.

- You may experience psychiatric reactions the first time you take Fluoxine. If you suffer from depression or psychosis, your symptoms may become worse under treatment with Fluoxine. In rare cases, depression or psychosis can progress to thoughts a suicide, suicide attempts, or completed suicide. If this happens, stop taking Fluoxine 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 Fluoxine and contact your doctor immediately.
- Diarrhoea may develop while you are taking antibiotics, including Fluoxine, 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 Fluoxine 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 Fluoxine if you have to provide a blood or urine sample.
- Fluoxine 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 Fluoxine and contact your doctor immediately.
- Fluoxine 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 Fluoxine. Avoid exposure to strong sunlight, or artificial UV light such as sunbeds**.**

Other medicines and Fluoxine

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

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

The following medicines are known to interact with Fluoxine in your body. Taking Fluoxine 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)

- metoclopramide (for nausea and vomiting)
- omeprazole (used for reducing the acid level in your stomach)
- ciclosporin (for skin conditions, rheumatoid arthritis and in organ transplantation)
- glibenclamide (for diabetes)
- duloxetine (for incontinence (Stress Urinary Incontinence (SUI))
- lidocaine (for heart conditions and anaesthetic use)
- sildenafil (e.g; for erectile dysfunction)
- 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.

Fluoxine may increase the levels of the following medicines in your blood:
- pentoxifylline (for circulatory disorders)
- caffeine

Some medicines reduce the effect of Fluoxine. 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 Fluoxine about two hours before or no sooner than four hours after them.

Fluoxine with food and drink
Unless you take Fluoxine 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 breastfeeding
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 Fluoxine during pregnancy. Do not take Fluoxine during breast-feeding because ciprofloxacin is excreted in breast milk and can be harmful for your child.

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

3. HOW TO TAKE FLUOXINE

Your doctor will explain to you exactly how much Fluoxine 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.

Always take Fluoxine 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 Fluoxine.
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 Fluoxine 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 Fluoxine.

If you take more Fluoxine 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 Fluoxine
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 Fluoxine
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, Fluoxine can cause side effects, although not everybody gets them.
If at any time, you have thoughts of suicide or self-harm, stop taking Fluoxine and contact your doctor or go to an hospital immediately.
Common side effects (may affect up to 1 in 10 people):
- nausea, diarrhoea
- joint pains in children

Uncommon side effects (may affect up to 1 in 100 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 up to 1 in 1,000 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 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
- increased levels of the enzyme amylase

Very rare side effects (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); 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)

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 (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)

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 FLUOXINE

Keep out of the sight and reach of children.
Do not use Fluoxine 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.
Store in the original package in order to protect from light, moisture and heat
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 Fluoxine contains
FLUOXINE 500: Each film-coated tablet contains 500 mg ciprofloxacin (as ciprofloxacin hydrochloride).
FLUOXINE 750: Each film-coated tablet contains 750 mg ciprofloxacin (as ciprofloxacin hydrochloride).
The other ingredients are: maize starch, microcrystalline cellulose, sodium methyl parahydroxybenzoate (E219), sodium propyl parahydroxybenzoate (E217), talc, magnesium stearate, colloidal anhydrous silica, sodium starch glycolate, croscarmellose sodium, hydoxypropylmethylcellulose, titanium dioxide (E171), macrogol 6000., tartrazine (E102) for FLUOXINE 500.

What Fluoxine looks like and contents of the pack
FLUOXINE 500: Yellow, elongated, biconvex and scored tablet.
FLUOXINE 750: White, elongated, biconvex and scored tablet.
Pack size of 10 tablets packaged in PVC/Aluminium blisters.

Fluoxine® is a trademark of:
Exphar S.A. Zoning Industriel de Nivelles Sud - Zone 2
Avenue Thomas Edison 105
1402 Thines, Belgique
Phone +32.067.68.84.05
Fax +32.067.68.84.19

Manufacturer
Gracure Pharmaceuticals Ltd., E-1105 Industrial area, Phase III, Bhiwadi (Raj) India.

This leaflet was last updated in 01/2018.