PATIENT INFORMATION LEAFLET

FLUOXINE T 500 mg/ 600 mg
Ciprofloxacin (as ciprofloxacin hydrochloride/Tinidazole

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 questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may arm 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 it this leaflet:

1. WHAT FLUOXINE T IS AND WHAT IT IS USED FOR?

FLUOXINE T contains a combination of antibiotics, ciprofloxacin, belonging to the family of quinolones, and tinidazole, belonging to the family of nitro-imidazole derivatives. FLUOXINE T is indicated in infections caused by germs that are sensitive to the active ingredients and for which ciprofloxacin- or tinidazole-based mono-therapies are not effective, such as:

- Chronic pouchitis and/or pouchitis resistant to the other treatment.
- Pelvic inflammatory disease.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE FLUOXINE T?

Do not take FLUOXINE T if:

- You are allergic to one of the active substances, to other quinolone drugs, drug chemically related to 5-nitro-imidazole derivatives, or to other ingredients of this medicine (listed in section 6).
- If you are taking tizanidine (see “Other medicine and FLUOXINE T”).
- You are in the first 13 weeks of pregnancy or trying to become pregnant.
- You are breast-feeding.
- You have a blood disorder or a history of blood disorders.
- You have central nervous system (CNS) disease, including epilepsy.

Warnings and precautions:

Concomitant consumption of drinks containing alcohol should be avoided during the treatment and at least 3 days after discontinuation due to the risk of adverse reactions (see also section : “FLUOXINE T with food and drink”).

Strictly follow the indications given by your doctor, specifically the treatment duration. Talk to your doctor if the following warnings are or have been applicable to you.

Talk to your doctor before taking FLUOXINE T

- If you ever had kidney problems, because your treatment may need to be adjusted.
- If you suffer from epilepsy or other neurological conditions.
- If you have history of tendon problems during previous treatment with antibiotics such as FLUOXINE T.
- If you are diabetic because you may experience a risk of hypoglycaemia with FLUOXINE T.
- 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 FLUOXINE T, 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 very slow heart rhythm (called "bradycardia"), have a weak heart (heart failure), have 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 FLUOXINE T").
- If you or a member of your family is known to have a deficiency in glucose-6-phosphate dehydrogenase (G6DP), since you may experience a risk of anaemia with ciprofloxacin.

While taking FLUOXINE T

Tell your doctor immediately if any of the following occurs while taking FLUOXINE T. You doctor will decide whether treatment with FLUOXINE T 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 stand up. **If this happens, stop taking FLUOXINE T 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 FLUOXINE T therapy. At the first sign of any pain or inflammation, stop taking FLUOXINE T 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 (convulsions). If this happens, stop taking FLUOXINE T and contact your doctor immediately.
- You may experience psychiatric reactions the first time you take FLUOXINE T. If you suffer from depression or psychosis, your symptoms may become worse under treatment with FLUOXINE T. In rare cases, depression or psychosis can progress to self-mutilation or suicide ideation, if this happens, stop taking FLUOXINE T and contact your doctor immediately or go to the hospital.
- You may experience symptoms of neuropathy such as pain, burning, tingling, numbness and/or weakness. If this happens, stop taking FLUOXINE T and contact your doctor immediately.

- 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 taking antibiotics, including ciprofloxacin, 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 T immediately, as this can be life-threatening. Do not take medicine that stop or slow down bowel movements and contact your doctor.
- Tell your doctor or laboratory staff that you are taking FLUOXINE T 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.
- FLUOXINE T 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 T and contact your doctor immediately.
- FLUOXINE T 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 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 assessment should be carried out in order verify if there is a drop in white blood cells (agranulocytosis). It is important to inform you doctor about your medicine.
- Your skin becomes more sensitive to sunlight or ultraviolet (UV) light when taking FLUOXINE T. Avoid exposure to strong sunlight, or artificial UV light such as sunbeds.

Other medicines and FLUOXINE T

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

- Tinidazole and other similar chemical compounds may increase the activity of medicines to thin your blood and your will adapt their dosage if required.
  Do not take FLUOXINE T together with tizanidine, because this may cause side effects such as low blood pressure and sleepiness (see section 2 “Do not take FLUOXINE T”).

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

- Warfarine of other anticoagulants (to thin the blood).
- Probenecid (for gout).
- Methotrexate (for certain type of cancer, psoriasis, rheumatoid arthritis).
- Theophylline (for breathing problems).
- Tizanidine (for muscle spasticity in multiple sclerosis).
- Clozapine and olanzapine (antipsychotics).
- Ropinirole (for Parkinson’s disease).
- Phenytoin (for epilepsy).
- Metoclopramide (for nausea and vomiting).
- Ciclosporin (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-arrhythmic (e.g. quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, dofetilide, ibutilide).
    - Tricyclic antidepressant (for depression).
    - Some macrolides (for the treatment of infections).
    - Some antipsychotics.

FLUOXINE T may increase the level 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 anaesthetic use).
- Sildenafil (for erectile dysfunction).

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

FLUOXINE T with food and drink
Unless you take FLUOXINE T during meals, do not eat or drink any dairy product (such as milk and yoghurt) or drinks with added calcium when you take the tablets, as they may affect the absorption of one of the active substances.
You should not drink wine, beer or spirits during treatment and for 3 days after stopping treatment with FLUOXINE T. The combination may cause flushing, stomach cramps, vomiting (being sick) and palpitation (pounding heart).
You should take FLUOXINE T during or after a meal.

Pregnancy and breast-feeding
You should not take FLUOXINE T if you are in the first 13 weeks of pregnancy. During second or third quarter, it should only be taken under strict advice of your doctor. If you are pregnant of 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. Do not take FLUOXINE T during breast-feeding because ciprofloxacin and tinidazole are both excreted in breast milk and can be harmful to your child. You should wait l at least 3 days before restarting breast-feeding after stopping FLUOXINE T.

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

3. HOW TO TAKE FLUOXINE T?

Follow strictly the instructions of your doctor. Your doctor will explain to you exactly how much FLUOXIN T 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 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 FLUOXINE T.

a) Swallow the tablets with plenty of fluid. Do not chew the tablets because theyt taste bad.
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 T 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 this medicine.
Andult

- Chronic pouchitis or those resistant to other treatment: 1 tablet of Fluoxine T, twice a day for 4 weeks (1,000 mg og ciprofloxacine +1,200 mg of tinidazole per day for 4 weeks).
- Upper genital infections: 1 tablet of Fluoxine T twice a day for 7 days (500 mg of ciprofloxacin + 600 mg of tinidazole twice a day for 7 days).

If you forget to take FLUOXINE T
If you forget to take FLUOXINE T, take it as soon as you can. Take the next dose at the right time. Do not take a double dose to make up for a forgotten one. Be sure to complete your course of treatment.

If you take more FLUOXINE T 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. In case of overdose, supportive symptomatic treatment should be initiated. Gastric lavage can be useful.

If you stop taking FLUOXINE T
Take FLUOXINE T for the full time of treatment, even when you begin to feel better. If you stop taking this medicine too soon, your infection may return or get worse. You might also develop resistance to the antibiotic. If you have any further questions about the use of this product, ask your doctor or pharmacist for advice.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Common (may affect up to 1 in 10 people):

- Nausea, diarrhoea.

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, 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 pains 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 (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, leucytosis, 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 (angioedema).
- Increased blood sugar (hyperglycemia).
- Decreased blood sugar (hypoglycaemia) (see section “warning and precaution”).
- 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, tremors, seizures (see section 2 “warnings and precautions”), or giddiness.
- Eyesight problems including double vision.
- Tinnitus, loss of hearing, impaired hearing.
- Rapid heartbeat (tachycardia).
- Expansion of blood vessels (vasodilatation), low blood pressure, or fainting.
- Shortness of breath, including asthmatic symptoms.
- Liver disorders, jaundice (cholestatic icterus), or hepatitis.
- Sensitivity to light (see section “warning and precautions”).
- Muscle pain, inflammation of the joints, increased muscle tone or cramp.
- Kidney failure, blood or crystals in the urine (see section 2 “warning 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 cells (agranulocytosis); a drop in the number of red blood cells and

platelets (pancytopenia), which may be fatal; a 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 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 vessels (vasculitis).
- Pancreatis.
- 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):
- Trouble associated with the nervous system such as pain, burning, tingling, numbness and/or weakness in extremities (peripheral neuropathy and polyneuropathy).
- Abnormal fast heart rhythm, life-threatening irregular heart rhythm, alteration of the heart rhythm (called 'prolongation of QT interval', seen on ECG, recording the electrical activity of the heart).
- Pustular rash.
- Influence on blood clotting (in patients treated with vitamin K antagonists).

Tinidazole can cause other side effects such as:
Mild gastro-intestinal adverse reactions, such as loss of appetite, metallic taste, diarrhoea, nausea abdominal pain and vomiting, headache, fatigue, fever, villous tongue, tongue inflammation, flush, tingling, sensory disorders, lack of sensibility and dark urine.

Allergic reactions, sometimes serious, can rarely occur : skin rash, pruritus, urticaria and angio-neurotic oedema and anaphylactic shock.

Severe skin reactions and mouth inflammation have rarely been reported.

Neurological troubles caused by tinidazole include dizziness, vertigo, seizure (rarely) and lack of movement co-ordination. Should neurological disorder occur, treatment should be discontinued.

Transient decrease in white blood cells and modifications of laboratory values (potential sign of allergic reaction) have also been reported.

During the treatment an opportunistic vaginal infection caused by Candida albicans may appear

Reporting 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 the national reporting system.

5. HOW TO STORE FLUOXINE T?

Keep all medicines out of the reach and sight of children.
Do not store above 30 °C. Store in the original package to protect from light.
Do not take this medicine after the expiry date stamped on the pack after EXP. The expiry date refers to the last day of the month.
Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

The active substances are ciprofloxacin (as ciprofloxacin hydrochloride) and tinidazole.
The other ingredients are: microcrystalline cellulose, maize starch, talc, magnesium stearate, anhydrous colloidal silica, sodium starch glycolate, crospovidone, opadry II white (E171).

What FLUOXINE T looks like and contents of the pack
White coloured, film-coated, capsule-shaped tablets, plain on one side and with a breakline on the other side.
Box of 10 tablets in blister (PVC/Aluminium).

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder
Exphar sa
Avenue Franklin Roosevelt 104 Bte 20
1330 RIXENSART
BELGIUM
Phone : +32 2 344.48.70
Fax: +32 2 346.03.14

Manufacturer
Gracure Pharmaceuticals Ltd., E-1105, Industrial Area, Phase-III,
Bhiwadi, Dist. Alwar (Raj.)
INDIA
Phone: +91 11 25920748
Fax: +91 11 25920747

Category of distribution: prescription only medicines.
Leaflet revision date: 02/2016