PACKAGE LEAFLET: INFORMATION FOR THE USER

Truoxin 250mg Film-Coated Tablets
Truoxin 500mg Film-Coated Tablets
Ciprofloxacin

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 and you should not pass it on to others. It may harm them, even if their symptoms 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 in this leaflet:

1. WHAT TRUOXIN FILM-COATED TABLETS ARE AND WHAT THEY ARE USED FOR

The active ingredient, **ciprofloxacin**, belongs to a group of medicines called quinolone antibiotics. Truoxin film-coated tablets are used to treat infections caused by susceptible bacteria.

Adults

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

- respiratory tract infections, e.g. pneumonia, bronchitis, worsening of symptoms of cystic fibrosis
- long lasting or recurring ear or sinus infections
- urinary tract infections
- gastro-intestinal infections, e.g. infective diarrhoea, travellers' diarrhoea
- intra-abdominal infections
- genital tract infections in men and women e.g. gonorrhoea, a commonly occurring sexually transmitted disease
- skin and soft tissue infections
- bone and joint infections
- to prevent infections due to the bacterium *Neisseria meningitidis*
- anthrax inhalation exposure

Children and adolescents

Truoxin film-coated tablets can also be used in children and adolescents, under medical supervision, to treat the following bacterial infections:

- cystic fibrosis and respiratory tract (lung) infection caused by a bacteria called *P. aeruginosa*
- complicated urinary tract infections, including infections that have reached the kidneys (pyelonephritis)
- anthrax inhalation exposure

Your doctor may also recommend Truoxin to treat other specific severe infections when they consider it necessary.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TRUOXIN FILM-COATED TABLETS

DO NOT take Truoxin:

- if you are sensitive (allergic) to ciprofloxacin, other quinolone antibiotics or any of the other ingredients in these tablets listed in section 6
- if you are taking tizanidine for spasticity associated with multiple sclerosis (MS) or injury or diseases of the spinal cord (see section 2: Other medicines and Truoxin).

Warnings and precautions

Before taking this medicine

You should not take fluoroquinolones/quinolone antibacterial medicines, including Truoxin, if you have experienced any serious adverse reaction in the past when taking a quinolone or fluoroquinolone. In this situation, you should inform your doctor as soon as possible.

Talk to your doctor before taking Truoxin:

- if you have ever had a problem with your kidneys, tell your doctor before taking Truoxin film-coated tablets. Your doctor may wish to change your dose to allow for any reduced kidney function.
- you should drink plenty of liquid whilst taking Truoxin film-coated tablets in order to avoid a kidney problem called crystalluria. Crystalluria arises in people taking Truoxin film-coated tablets who become dehydrated. In this case, people who are affected experience pain or discomfort when passing urine which results from the production of tiny crystals formed in the kidneys. Should you experience these symptoms you should contact your doctor.
- if you have had previous problems with your liver, tell your doctor. He/she may want to check for any changes in its function. Also consult your doctor if you have yellowing of the whites of the eyes or skin.
- if you have previously had 'fits' or suffer from epilepsy or if you have suffered other conditions related to nervous supply to the brain, tell your doctor before taking Truoxin film-coated tablets.
- if you have a history of tendon inflammation especially if these have been associated with previous use of antibiotics.
- if you are a diabetic because you may experience a risk of hypoglycaemia with ciprofloxacin.
- if you have myasthenia gravis (a type of muscle weakness) because symptoms can be exacerbated.
- if you feel depressed, anxious or confused whilst taking your medicine. If any of these feelings progress to you actually physically harming or wanting to physically harm yourself you should stop taking this medicine immediately and consult your doctor.

- if you develop severe and persistent diarrhoea, which may contain blood and mucus whilst you are taking Truoxin film-coated tablets, or after stopping taking it, you should consult your doctor immediately as you may be suffering from the condition pseudomembranous colitis which can sometimes be life threatening. Medicines which may slow or stop bowel movements must not be taken.
- if you have heart problems. Caution should be taken when using this kind of medicine, 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 *Other medicines and Truoxin*).
- if you have been diagnosed with an enlargement or "bulge" of a large blood vessel (aortic aneurysm or large vessel peripheral aneurysm).
- if you have experienced a previous episode of aortic dissection (a tear in the aorta wall).
- if you have a family history of aortic aneurysm or aortic dissection or other risk factors or predisposing conditions (e.g. connective tissue disorders such as Marfan syndrome, or vascular Ehlers Danlos syndrome, or vascular disorders such as Takayasu arteritis, giant cell arteritis, Behcet's disease, high blood pressure, or known atherosclerosis).
- if you have a family history of or problem with glucose-6-phosphate dehydrogenase (G6PD) activity, since you may experience a risk of anaemia with ciprofloxacin.

For the treatment of some genital 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.

If you go into hospital for surgery, have dental treatment which requires anaesthetic or you need to provide a blood or urine sample, tell the doctor or dentist that you are taking Truoxin film-coated tablets.

While taking Truoxin
Tell your doctor immediately, if any of the following occurs while taking Truoxin. Your doctor will decide whether treatment with Truoxin 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 Truoxin and contact your doctor immediately.
- If you feel sudden, severe pain in your abdomen, chest or back, go immediately to an emergency room.
- Pain and swelling in the joints and inflammation or rupture of tendons may occur rarely. Your risk is increased if you are elderly (above 60 years of age), have received an organ transplant, have kidney problems or if you are being treated with corticosteroids. Inflammation and ruptures of tendons may occur within the first 48 hours of treatment and even up to several months after stopping of Truoxin therapy.

At first sign of pain or inflammation of a tendon (for example in your ankle, wrist, elbow, shoulder or knee), stop taking Truoxin, contact your doctor 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 Truoxin and contact your doctor immediately.
- You may experience psychiatric reactions the first time you take Truoxin. If you suffer from depression or psychosis, your symptoms may become worse under treatment with Truoxin. In rare cases, depression or psychosis can progress to thoughts of suicide, suicide attempts, or completed suicide. If this happens, stop taking Truoxin and contact your doctor immediately.
- You may rarely experience symptoms of nerve damage (neuropathy) such as pain, burning, tingling, numbness and/or weakness especially in the feet and legs or hands and arms. If this happens, stop taking Truoxin and contact your doctor immediately in order to prevent the development of potentially irreversible conditions.
- Quinolone antibiotics may cause an increase of your blood sugar levels above normal levels (hyperglycaemia), or lowering of your blood sugar levels below normal levels, potentially leading to loss of consciousness (hypoglycaemic coma) in severe cases (see section 4). This is important for people who have diabetes. If you suffer from diabetes, your blood sugar should be carefully monitored.
- Diarrhoea may develop while you are taking antibiotics, including Truoxin, 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 Truoxin immediately, as this can be life-threatening. Do not take medicines that stop or slow down bowel movements and contact your doctor.
- If your eyesight becomes impaired or if your eyes seem to be otherwise affected, consult an eye specialist immediately.
- Tell the doctor or laboratory staff that you are taking Truoxin 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.
- Truoxin 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 Truoxin and contact your doctor immediately.
- Truoxin 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.
- Your skin becomes more sensitive to sunlight or ultraviolet (UV) light when taking Truoxin. Avoid exposure to strong sunlight, or artificial UV light such as sunbeds.

Prolonged, disabling and potentially irreversible serious side effects

Fluoroquinolone/quinolone antibacterial medicines, including Truoxin, have been associated with very rare but serious side effects, some of them being long lasting (continuing months or years), disabling or potentially irreversible. This includes tendon,

muscle and joint of the upper and lower limbs, difficulty in walking, abnormal sensations such as pins and needles, tingling, tickling, numbness or burning (paraesthesia), sensory disorders including impairment of vision, taste and smell, and hearing, depression, memory impairment, severe fatigue, and severe sleep disorders.

If you experience any of these side effects after taking Truoxin, contact your doctor immediately prior to continuing treatment. You and your doctor will decide on continuing the treatment considering also an antibiotic from another class.

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

Do not take Truoxin with tizanidine, because this may cause side effects such as low blood pressure and sleepiness (see section 2: Do not take Truoxin film-coated tablets).
Certain medicines are known to affect the action of ciprofloxacin and are best avoided whilst taking it. Taking ciprofloxacin together with these medicines can influence the effect of those medicines and alter how they work in the body. It can also increase the probability of experiencing side effects.
Tell your doctor if you are taking any of the following:

- **vitamin K antagonists** (such as **warfarin**, **acenocoumarol**, **phenprocoumon** or **fluindione**) or other oral anticoagulants (**drugs that thin the blood)**
- any medicine used to relieve pain and inflammation (e.g. fenbufen) except for aspirin.
- **probenecid** (for gout) **or metoclopramide** (for nausea and vomiting) as these drugs may affect the level of Truoxin film-coated tablets in your blood.
- **Methotrexate** (for certain types of cancer, psoriasis, rheumatoid arthritis) at the same time as Truoxin film-coated tablets, remind your doctor as he/she may want to do additional blood tests.
- **theophylline** for asthma, remind your doctor as he/she should monitor the levels of theophylline in your blood. This is particularly important if you suffer from 'fits' or convulsions. High levels of theophylline in the blood may be life-threatening.
- **clozapine** and **olanzapine** for psychosis
- **ropinirole** (for Parkinson's disease)
- **phenytoin** for epilepsy, remind your doctor as the levels of this medicine may be altered if used at the same time as Truoxin film-coated tablets.
- **ciclosporin** (for skin conditions, rheumatoid arthritis and in organ transplantation)
- **glibenclamide** for diabetes, remind your doctor as ciprofloxacin sometimes increase the ability of glibenclamide to lower blood sugar and may result in hypoglycaemia.
- **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**.
- **zolpidem** (for sleep disorders)

Truoxin film-coated tablets may **increase** the levels of the following medicines in your blood:

- **pentoxifylline** (for circulatory disorders)
- **caffeine**
- **tacrine** (for dementia)
- **lidocaine** (for heart conditions or anaesthetic use)

- **sildenafil (**e.g. for erectile dysfunction)
- **duloxetine** (for depression, diabetic nerve damage or incontinence)
- **agomelatine** (for depression)

Some medicines **reduce** the effect of Truoxin film-coated tablets. Tell your doctor if you wish to take:

- **omeprazole**
- **sucralfate**
- **antacids** for indigestion
- any other preparations containing **aluminium, calcium, magnesium or iron**
- **polymeric phosphate binder** (e.g. sevelamer or lanthanum carbonate).

If these preparations are essential, take Truoxin film-coated tablets about two hours before or no sooner than four hours after them. If you take multivitamins or minerals, check that they do not contain iron, calcium or magnesium. If they do, your doctor may want you to stop taking them while you are taking Truoxin film-coated tablets.

Truoxin film-coated tablets with food and drink
Unless you take Truoxin during meals, do not eat or drink any dairy products (such as milk or yogurt) or drinks with added calcium when you take the tablets, as they may affect the absorption of the active substance.
Avoid drinking alcohol while taking Truoxin film-coated tablets.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to become pregnant ask your doctor or pharmacist for advice before taking Truoxin film-coated tablets as it is not recommended for use under these conditions. If you have already told your doctor, follow his/her instructions carefully.
Do not take Truoxin film-coated tablets during breast-feeding because ciprofloxacin is excreted in breast milk and can be harmful for your child.

Driving and operating machines
Taking Truoxin film-coated tablets can make you feel dizzy and/or impair your concentration. If this happens to you, you should avoid driving a vehicle or operating machinery while taking Truoxin film-coated tablets**.** If in doubt, talk to your doctor.

3. HOW TO TAKE TRUOXIN FILM-COATED TABLETS

Your doctor will explain to you exactly how much Truoxin 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 Truoxin.

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 Truoxin 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 this medicine.

If you take more Truoxin film-coated tablets than you should
If you take more than the prescribed dose, get medical help immediately, and if possible, take your tablets or the box with you to show the doctor.

If you forget to take Truoxin film-coated tablets
If you have forgotten to take your medicine, 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 the missed one. If you are at all concerned, consult your doctor or pharmacist.

If you stop taking Truoxin film-coated tablets
It is important that you finish the course of treatment even if you begin to feel better after a few days. Do not stop taking Truoxin film-coated tablets before you have finished all the tablets prescribed, as 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 about the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Truoxin film-coated tablets can cause undesirable effects, although not everybody gets them.

The following side effects have been observed during treatment with ciprofloxacin.

STOP taking your medicine IMMEDIATELY and tell your doctor, or go to your nearest hospital casualty department if you experience:

- **allergic oedema/angio-oedema** (swelling, large, localized, painless swellings under the skin), **anaphylactic reaction** (a serious allergic reaction which causes swelling of the face, lips tongue and/or throat which may cause difficulties in swallowing /breathing), **allergic reactions** (rash, itching, hives or fever), **pustular rash**, **unspecific blistering** (see Section 2: Warnings and precautions)
- **antibiotic associated colitis** (severe diarrhoea possibly containing blood and/or mucus, may develop into complications that are life-threatening)
- **kidney failure, liver function impairment/failure** (transient hepatic impairment, Jaundice (a yellowing of the whites of the eyes or skin), haematuria (blood in urine))
- **pancreatitis** (inflammation of the pancreas leading to severe pain in the upper abdomen or back)
- **liver failure** (liver necrosis) very rarely progressing to life-threatening hepatic failure
- various skin eruptions or rashes (e.g. the potentially fatal Stevens-Johnson syndrome or toxic epidermal necrolysis)

- **anaphylactic shock** (drop in blood pressure possibly leading to collapse, purplish red spots on the skin)

If you experience an allergic reaction, stop the treatment and seek medical advice immediately.

If you notice yellowing of your skin or any changes in your urine output or appearance, possibly accompanied by kidney pain, or pain in your abdomen or back, seek medical advice immediately. Your doctor may check your blood for signs of liver problems.

Tell your doctor straight away if you notice any of the following side effects:

Common: may affect up to 1 in 10 people
- **nausea** (feeling sick)
- **diarrhoea**

Uncommon: may affect up to 1 in 100 people
- unspecific **pain, feeling unwell, fever**
- **headache, dizziness, sleep disorders, taste disorders** (usually reversible upon discontinuation of treatment)
- **psychomotor hyperactivity** (extreme restlessness accompanied with an involuntarily, somewhat rhythmic muscle contraction) / **agitation** (unpleasant state of extreme arousal)
- **anorexia** (loss of appetite, no desire to eat), **vomiting, gastrointestinal and abdominal pain, dyspepsia** (upset stomach/ indigestion, heartburn), **flatulence** (wind)
- **kidney problems, liver enzyme impairment** (transient increase in transaminases, increased bilirubin)
- **rash, pruritus** (feeling itchy, itchy skin), urticaria (severe itching of the skin with raised lumps - hives)
- **arthralgia** (joint pain) in adults
- **eosinophilia** (increase in white blood cells)
- **increase in blood alkaline phosphatase**
- **thrush** (Candida infections)
- **Musculoskeletal pain** (joint pain, extremity pain, back pain, chest pain)
- **Mycotic Superinfections** (a second infection superimposed on an earlier one)

Rare: may affect up to 1 in 1000 people
- **oedema** (swelling), **hyperhidrosis** (excessive sweating), **paraesthesia**, **dysaesthesia & hypoaesthesia**, (tingling or burning sensation, numbness, or distortion of the senses across the body and/or decreased sensitivity to touch), **tremor**, s**eizures (fits)** (see section 2: Warnings and precautions), **somnolence** (sleepiness)
- **confusion and disorientation**, **anxiety** reaction, abnormal dreams, depression (potentially culminating in suicidal ideations/thoughts or suicidal attempts and completed suicide) (see section 2), Hallucinations
- **vertigo** (sensation of dizziness, spinning or falling over) **visual disturbances**, **hearing loss**, hearing impaired, **tinnitus** (sound within the human ear but the absence of corresponding external sound to others)
- **dyspnoea** (shortness of breath) including asthmatic symptoms, **tachycardia** (rapid or accelerated heart beat)

- **vasodilation** (widening of blood vessels), **hypotension** (abnormally low blood pressure), **syncope** (loss of consciousness)
- **dysphagia** (difficulty in swallowing), **hyperglycaemia** (high blood sugar) which may increase your need to pass water or drink more than normal), **hypoglycaemia** (decreased blood sugar). See Section 2: "Warnings and precautions".
- **Antibiotic colitis** (inflammation of the colon which is most often related to recent antibiotic use. Very rarely with possible fatal outcome).
- **crystalluria** (crystals causing pain and discomfort when passing water), **tubulointerstitial nephritis** (inflammation of the kidneys)
- **photosensitivity reactions** (skin more sensitive to sunlight than normal), see Section 2: "Warnings and precautions"
- **myalgia** (muscle pain), **arthritis** (inflammation of joints), **increased muscle tone and cramping**
- **changes in blood count; leukopenia** (low white blood cell count), **anaemia** (low level of red oxygen carrying blood cells), **neutropenia** (a condition of an abnormally low number of white blood cells), **leukocytosis** (a raised white blood cell count above the normal range in the blood), t**hrombocytopenia** (a reduced platelet (thrombocyte) count), **thrombocythaemia** (an increased level of platelets, which are essential for blood clotting)
- **increase levels of the enzyme amylase**
- **cholestatic icterus** (Jaundice caused by thickened bile or bile plugs in the small biliary passages of the liver.)

Very rare: may affect up to 1 in 10000 people

- **migraine** (high fluid pressure within the skull), **disturbed coordination**, **smell disorders, pressure on the brain** (intracranial pressure and pseudotumor cerebri), **Gait disturbance** (walking abnormality)
- **visual colour distortions**
- **Serum sickness-like reaction** (rash, arthritis, and fever)
- **petechiae** (small (1-2mm) red or purple spot on the body, caused by minor broken capillary blood vessels), **erythema multiforme minor** (mild rash)
- **muscular weakness**, **tendonitis** (inflammation of a tendon), **tendon rupture** (predominantly Achilles tendon) (see section 2: Warnings and precautions), worsening of the symptoms of myasthenia gravis
- **psychotic reactions** (potentially culminating in suicidal ideations/thoughts or suicidal attempts and completed suicide) (see section 2)
- **haemolytic anaemia** (a form of anaemia due to haemolysis, the abnormal breakdown of red blood cells), **agranulocytosis** (a marked decrease in the number of white blood cells type – granulocytes important in immunity), **pancytopenia** (a deficiency of all types of blood cells, including white blood cells, red blood cells and platelets), which may be fatal and **bone marrow depression**, which may also be fatal (see section 2: Warnings and precautions).

Not known: frequency cannot be estimated from the available data

- **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)
- **troubles associated with the nervous system** such as pain, burning, tingling, numbness and/or weakness in extremities (peripheral neuropathy and polyneuropathy)

- **influence on blood clotting** (INR) in patients on Vitamin K antagonist therapy
- **feeling highly excited (mania)** or feeling great optimism and over activity (hypomania)
- **A drug reaction that causes rash,** fever, inflammation of internal organs, hematologic abnormalities and systemic illness (DRESS Drug Reaction with Eosinophilia and Systemic Symptoms, AGEP Acute Generalised Exanthematous Pustulosis).
- **Syndrome associated with impaired water excretion and low levels of sodium (SIADH)**
- Loss of consciousness due to severe decrease in blood sugar levels (hypoglycaemic coma). See section 2

This medicine may make your skin become more sensitive to sunlight or UV light. You should avoid exposure to strong sunlight and should not use a sun-bed or other means of UV exposure.

This medicine may cause an allergic reaction which can occur soon after starting to take the tablets and occasionally after the first time the tablets are taken. (See section 4. Possible side effects)

Very rare cases of long lasting (up to months or years) or permanent adverse drug reactions, such as tendon inflammations, tendon rupture, joint pain, pain in the limbs, difficulty in walking, abnormal sensations such as pins and needles, tingling, tickling, burning, numbness or pain (neuropathy), depression, fatigue, sleep disorders, memory impairment, as well as impairment of hearing, vision, and taste and smell have been associated with the administration of quinolone and fluoroquinolone antibiotics, in some cases irrespective of pre-existing risk factors.

Reporting of 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2;
Tel: +353 1 6764971; Fax: +353 1 6762517.
Website: www.hpra.ie; E-mail: medsafety@hpra.ie.
By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE TRUOXIN FILM-COATED TABLETS

Keep all medicines out of the sight and reach of children. Your medicines can harm them.

This medicinal product does not require any special storage conditions.

Do not take this medicine after the expiry date shown on the carton and on the blister. The expiry date refers to the last day of the month. Any out of date medicines should be returned to your pharmacist for disposal.

If you notice any visible signs of deterioration in the tablets, such as chipped, broken or discoloured tablets, take them to your pharmacist for advice before taking them.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Truoxin film-coated tablets contain
The name of your medicine is **Truoxin Film-Coated Tablets**. Each Truoxin 250mg film-coated tablet contains 250mg of the active ingredient ciprofloxacin (as ciprofloxacin hydrochloride). Each Truoxin 500mg film-coated tablet contains 500mg of the active ingredient ciprofloxacin (as ciprofloxacin hydrochloride). The other ingredients are microcrystalline cellulose, crospovidone, colloidal anhydrous silica, magnesium stearate, hypromellose, macrogol 400 and titanium dioxide (E171).

What Truoxin film-coated tablets look like and contents of the pack
Truoxin 250mg Film-coated Tablets are white or yellowish, 11mm round, biconvex, film-coated tablets, scored on both sides and side wall scored, marked C250 on one side.

Truoxin 500mg Film-coated Tablets are white or yellowish, 8.2 x 17mm oval, biconvex, film-coated tablets, scored on one side and side wall scored, marked C500 on one side.

Truoxin film-coated tablets are available from your pharmacist on prescription only in packs of 10 and 20 Film-coated Tablets.

The product Authorisation Holder is:
Fannin Limited, Fannin House, South County Business Park, Leopardstown, Dublin 18

PA Numbers: 1457/013/001-002

The Manufacturer is:
Actavis Ltd. BLB015-016 Bulebel Industrial Estate Zejtun ZTN 3000
MALTA

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This leaflet applies to Truoxin 250mg and 500mg Film-coated tablets only.

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