

Package Leaflet: Information for the user

Ciplox 250 mg film-coated Tablets
Ciplox 500 mg film-coated Tablets
Ciplox 750 mg 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 any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you 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 is in this leaflet:

- 1. What Ciplox is and what it is used for**
- 2. What you need to know before you take Ciplox**
- 3. How to take Ciplox**
- 4. Possible side effects**
- 5. How to store Ciplox**
- 6. Contents of the pack and other information**

1. What Ciplox is and what it is used for

Ciplox 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

Ciplox 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

Ciplox 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 Ciplox.

Children and adolescents

Ciplox 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

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

2. What you need to know before you take Ciplox

Do not take Ciplox:

- if you are allergic to ciprofloxacin, to other quinolone drugs or any of the other ingredients of this medicine (listed in section 6)
- if you are taking tizanidine (see section 2 ‘Other medicines and Ciplox’)

Warning and precautions

Talk to your doctor or pharmacist before taking Ciplox

Before taking this medicine

You should not take fluoroquinolone/quinolone antibacterial medicines, including Ciplox, 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.

Tell your doctor before taking Ciplox if you:

- have been diagnosed with an enlargement or "bulge" of a large blood vessel (aortic aneurysm or large vessel peripheral aneurysm).
- have experienced a previous episode of aortic dissection (a tear in the aorta wall).
- have been diagnosed with leaking heart valves (heart valve regurgitation).
- have a family history of aortic aneurysm or aortic dissection or congenital heart valve disease, or other risk factors or predisposing conditions (e.g. connective tissue disorders such as Marfan syndrome or Ehlers-Danlos syndrome, Turner syndrome, Sjögren's syndrome [an inflammatory autoimmune disease], or vascular disorders such as Takayasu arteritis, giant cell arteritis, Behcet's disease, high blood pressure, or known atherosclerosis, rheumatoid arthritis [a disease of the joints] or endocarditis [an infection of the heart]).
- 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 Ciplox
- are diabetic because you may experience a risk of hypoglycaemia with ciprofloxacin.
- have myasthenia gravis (a type of muscle weakness) because symptoms can be exacerbated.
- have heart problems. Caution should be taken when using this kind of medicine, if you were born 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 (a condition called 'bradycardia'), have a weak heart (heart failure), have a history of heart attacks (myocardial infarction), you are female or elderly or you are taking other medicines that results in abnormal ECG changes (see section 'Other medicines and Ciplox')
- 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 anaemia with ciprofloxacin.

For the treatment of some genital tract infections, your doctor can prescribe another antibiotic in addition to Ciplox. If there is no improvement in symptoms after 3 days of treatment, please consult your doctor.

While taking this medicine

Tell your doctor immediately, if any of the following occurs **while taking Ciplox**. Your doctor will decide whether treatment with Ciplox 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 Ciplox and contact your doctor immediately.**
- **Prolonged, disabling and potentially irreversible serious side effects**
Fluoroquinolone/quinolone antibacterial medicines, including Ciplox, 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 pain 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 Ciplox, 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.
- **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 Ciplox therapy. At the first sign of pain or inflammation of a tendon (for example in your ankle, wrist, elbow, shoulder or knee), stop taking Ciplox, contact your doctor and rest the painful area. Avoid any unnecessary exercise as this might increase the risk of a

tendon rupture.

- If you feel **sudden, severe pain in your abdomen, chest or back**, which can be symptoms of aortic aneurysm and dissection, go immediately to an emergency room. Your risk may be increased if you are being treated with systemic corticosteroids.
- If you start experiencing a **rapid onset of shortness of breath**, especially when you lie down flat in your bed, or you notice swelling of your ankles, feet or abdomen, or a new onset of heart palpitations (sensation of rapid or irregular heartbeat), you should inform a doctor immediately.
- 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 Ciplox and contact your doctor immediately.
- You may experience **psychiatric reactions** the first time you take Ciplox. If you suffer from **depression** or **psychosis**, your symptoms may become worse under treatment with Ciplox. In rare cases, depression or psychosis can progress to thoughts of suicide, suicide attempts, or completed suicide. If this happens, contact your doctor immediately.
- If you feel depressed, anxious or feel you want to **physically harm yourself** while taking Ciplox, stop taking this medicine and contact your doctor immediately.
- You may 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 Ciplox and contact your doctor immediately in order to prevent the development of potentially irreversible condition.
- 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 Ciplox, 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 Ciplox 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.
- Your skin becomes more **sensitive to sunlight or ultraviolet (UV) light** when taking Ciplox. Avoid exposure to strong sunlight, or artificial UV light such as sunbeds.
- Tell the doctor or laboratory staff that you are taking Ciplox 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.
- Ciplox 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, contact your doctor immediately.
- Ciplox 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.

Other medicines and Ciplox

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

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

The following medicines are known to interact with Ciplox in your body. Taking Ciplox 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, acenocoumarol, phenprocoumon and fluinidone) or other anti-coagulants (to thin the blood)
- probenecid (for gout)
- metoclopramide (for nausea and vomiting)
- omeprazole (for ulcers)
- methotrexate (for certain types of cancer, psoriasis, rheumatoid arthritis)
- theophylline (for breathing problems)
- tizanidine (for muscle spasticity in multiple sclerosis)
- olanzapine (an antipsychotic)

- clozapine (an antipsychotic)
- ropinirole (for Parkinson's disease)
- phenytoin (for epilepsy)
- cyclosporin (for skin conditions, rheumatoid arthritis and in organ transplantation)
- 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)

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

- pentoxifylline (for circulatory disorders)
- caffeine
- glibenclamide (for diabetes)
- duloxetine (for depression, diabetic nerve damage or incontinence)
- lidocaine (for heart conditions or anaesthetic use)
- sildenafil (for erectile dysfunction)
- agomelatine (for depression)

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

- antacids
- a medicine used to treat HIV (didanosine)
- 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 Ciplox about two hours before or no sooner than four hours after them.

Ciplox with food and drink

Any calcium taken as part of a meal, including dairy products and drinks rich in calcium (such as milk or yogurt) or fortified fruit juices (e.g. orange juice containing added calcium), will not significantly affect the absorption of this medicine. However, Ciplox tablets administered concurrently with dairy products and drinks rich in calcium when these dairy products or drinks are taken alone separately to meals, may reduce the effect of this medicine. Consequently, Ciplox tablets should be taken either 1-2 hours before or no sooner than 4 hours after dairy products or drinks rich in calcium taken alone separately to meals (see also Section 3)

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you might 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 Ciplox during pregnancy.

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

Driving and using machines

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

3. How to take Ciplox

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will explain to you exactly how much Ciplox you will have to take as well as how often and for how long. This will depend on the type of infection you have and how bad it is.

Tell your doctor if you suffer from kidney problems because your dose may need to be adjusted.

The treatment usually lasts from 5 to 21 days, but may take longer for severe infections. Take the tablets exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure how many tablets to take and how to take Ciplox.

- a. Swallow the tablets with plenty of fluid. Do not chew and crush the tablets because they do not taste nice. If you are not able to swallow the tablet, please inform your doctor, so that they could prescribe another formulation more suitable for you
- 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. You can take Ciplox during meals containing dairy products (such as milk or yogurt) or with drinks rich in calcium (e.g. calcium-fortified orange juice). However, **do not** take Ciplox at the same time as dairy products or drinks rich in calcium when these dairy products or drinks rich in calcium are taken alone separately to meals.
- d. Ciplox should be taken about one to two hours before or no sooner than four hours after dairy products or drinks rich in calcium taken alone separately to meals.

Remember to drink plenty of fluids while you are taking Ciplox.

If you take more Ciplox 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 Ciplox

If you forget to take Ciplox and it is:

- **6 hours or more** until your next scheduled dose, take your missed dose right away. Then take the next dose at your regular time.
- **Less than 6 hours** until your next scheduled dose, do not take the missed dose. Take the next dose at your regular time.

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 Ciplox

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 further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following section contains the most serious side effects that you can recognize yourself:

Stop taking Ciplox and contact your doctor immediately in order to consider another antibiotic treatment if you notice any of the following serious side effects:

Rare (may affect up to 1 in 1,000 people)

- Seizure (see Section 2: Warnings and precautions)

Very rare (may affect up to 1 in 10,000 people)

- Severe, sudden allergic reaction with symptoms such as tightness in the chest, feeling dizzy, sick or faint, or experience dizziness when standing up (anaphylactic reaction/shock) (see Section 2: Warnings and precautions)
- Muscle weakness, inflammation of the tendons which could lead to rupture of the tendon, particularly affecting the large tendon at the back of the ankle (Achilles tendon) (see Section 2: Warnings and precautions)
- A serious life-threatening skin rash, usually in the form of blisters or ulcers in the mouth, throat, nose, eyes and other mucous membranes such as genitals which may progress to widespread blistering or peeling of the skin (Stevens-Johnson syndrome, toxic epidermal necrolysis).

Not known (frequency cannot be estimated from the available data)

- Unusual feelings of pain, burning tingling, numbness or muscle weakness in the extremities (neuropathy) (see Section 2: Warnings and precautions)

- A drug reaction that causes rash, fever, inflammation of internal organs, hematologic abnormalities and systemic illness (DRESS Drug Reaction with Eosinophilia and Systemic Symptoms, AGEF Acute Generalised Exanthematous Pustulosis).

Other side effects which have been observed during treatment with Ciplox are listed below by how likely they are:

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

- nausea, diarrhoea
- joint pain and joint inflammation 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
- 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 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 ‘Warning 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) (see Section 2: Warnings and precautions)
- increased blood sugar (hyperglycaemia)
- decreased blood sugar (hypoglycaemia) (see Section 2: Warnings and precautions)
- confusion, disorientation, anxiety reactions, strange dreams, depression (potentially leading to thoughts of suicide, suicide attempts, or completed suicide) (see Section 2 ‘Warning and precautions’), or hallucinations
- pins and needles, unusual sensitivity to stimuli of the senses, decreased skin sensitivity, tremors, or giddiness
- eyesight problems (diplopia) including double vision (see Section 2 ‘Warning and precautions’)
- 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 ‘Warning and precautions’)
- muscle pain, inflammation of the joints, increased muscle tone, or cramping
- kidney failure, blood or crystals in the urine (see Section 2 ‘Warning and precautions’), urinary tract inflammation
- fluid retention or excessive sweating
- abnormal levels of a clotting factor (prothrombin) or increased levels of the enzyme amylase

Very rare side effects (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) (see Section 2: Warnings and precautions); 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 ‘Warning and precautions’)
- severe allergic reactions (anaphylactic reaction or anaphylactic shock, which can be fatal - serum sickness) (see Section 2 ‘Warning and precautions’)
- mental disturbances (psychotic reactions potentially leading to thoughts of suicide, suicide attempts or completed suicide) (see Section 2 ‘Warning 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)
- pancreatitis

- death of liver cells (liver necrosis) very rarely leading to life-threatening liver failure (see Section 2: Warnings and precautions)
- 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)
- worsening of the symptoms of myasthenia gravis (see Section 2 ‘Warning 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)
- feeling highly excited (mania) or feeling great optimism and over-activity (hypomania)
- 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.
- influence on blood clotting (in patients treated with Vitamin K antagonists)

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), fatigue, memory and concentration impairment, mental health effects (which may include sleep disorders, anxiety, panic attacks, depression and suicidal ideation), as well as impairment of hearing, vision, and taste and smell have been associated with administration of quinolone and fluoroquinolone antibiotics, in some cases irrespective of pre-existing risk factors.

Cases of an enlargement and weakening of the aortic wall or a tear in the aortic wall (aneurysms and dissections), which may rupture and may be fatal, and of leaking heart valves have been reported in patients receiving fluoroquinolones. See also section 2.

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, Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ciplox

Keep this medicine out of the sight and reach of children.

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date, which is stated on the carton label and blister foil after ‘EXP’. The expiry date refers to the last day of that month.

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 Ciplox contains

- The active substance is ciprofloxacin. Each film-coated tablet contains either 250 mg, 500 mg or 750 mg ciprofloxacin (as ciprofloxacin hydrochloride)
- The other ingredients are *tablet core*: microcrystalline cellulose, crospovidone, silica colloidal anhydrous, magnesium stearate; *Film coat*: hypromellose, macrogol 400, titanium dioxide (E171)

What Ciplox looks like and contents of the pack

Ciplox 250 mg are white or yellowish, 11 mm, circular, biconvex, film-coated tablets, scored on both sides and side-wall scored, marked “C250” on one side.

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

Ciplox 750 mg are white or yellowish, 10 x 19 mm, oval, biconvex, film-coated tablets, scored on one side and side-wall scored, marked “C750” on one side.

The tablets can be divided into equal halves.

Pack sizes

Blisters (Al/PVC)

Pack sizes are 6, 7, 10, 14, 20 (*only 250 mg and 500 mg*), 28, 30, 56, 60, 84, 90, 100, 120, 150 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Accord Healthcare Ireland Ltd,
Euro House,
Euro Business Park,
Little Island,
Cork T45 K857,
Ireland

Manufacturers

Actavis hf, Reykjavikurvegur 78, 220 Hafnarfjordur, Iceland
Actavis Ltd, BLB016 Bulebel Industrial Estate, Zejtun ZTN 3000, Malta
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Advice/medical education

Antibiotics are used to cure bacterial infections. They are ineffective against viral infections.

If your doctor has prescribed antibiotics, you need them precisely for your current illness.

Despite antibiotics, some bacteria may survive or grow. This phenomenon is called resistance: some antibiotic treatments become ineffective.

Misuse of antibiotics increases resistance. You may even help bacteria become resistant and therefore delay your cure or decrease antibiotic efficacy if you do not respect appropriate:

- dosages
- schedules
- duration of treatment

Consequently, to preserve the efficacy of this drug:

- 1 - Use antibiotics only when prescribed.
- 2 - Strictly follow the prescription.
- 3 - Do not re-use an antibiotic without medical prescription, even if you want to treat a similar illness.
- 4 - Never give your antibiotic to another person; maybe it is not adapted to her/his illness.
- 5 - After completion of treatment, return all unused drugs to your chemist's shop to ensure they will be disposed of correctly.