

PACKAGE LEAFLET

Package leaflet: Information for the patient

Ciprofloxacin Viatriis 100 mg film-coated tablets
Ciprofloxacin Viatriis 250 mg film-coated tablets
Ciprofloxacin Viatriis 500 mg film-coated tablets
Ciprofloxacin Viatriis 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 Ciprofloxacin Viatriis is and what it is used for
2. What you need to know before you take Ciprofloxacin Viatriis
3. How to take Ciprofloxacin Viatriis
4. Possible side effects
5. How to store Ciprofloxacin Viatriis
6. Contents of the pack and other information

1. What Ciprofloxacin Viatriis is and what it is used for

Ciprofloxacin Viatriis, contains the active substance ciprofloxacin, which is an antibiotic belonging to the fluoroquinolone family. Ciprofloxacin works by killing bacteria that cause infections. It only works with specific strains of bacteria.

Adults

Ciprofloxacin Viatriis is used in adults to treat the following bacterial infections:

- respiratory tract infections
- long lasting or recurring ear or sinus infections
- urinary tract infections
- genital tract infections in men and women
- gastro-intestinal tract infections and intra-abdominal infections
- skin and soft tissue infections
- bone and joint infections
- to prevent infections due to the bacterium *Neisseria meningitidis*
- anthrax inhalation exposure

Ciprofloxacin may also be used to treat patients with low white blood cell counts (neutropenia) who have a fever that is suspected to be caused by 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 ciprofloxacin.

Children and adolescents

Ciprofloxacin Viatris 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 (acute pyelonephritis)
- anthrax inhalation exposure

Ciprofloxacin 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 Ciprofloxacin Viatris

Do not take Ciprofloxacin Viatris:

- if you are allergic to ciprofloxacin, to other quinolone drugs (such as moxifloxacin, norfloxacin, ofloxacin or nalidixic acid) or any of the other ingredients of this medicine (listed in section 6)
- if you are taking tizanidine (see section 2 'Other medicines and Ciprofloxacin Viatris')

Warnings and precautions

Before taking this medicine

You should not take fluoroquinolone/quinolone antibacterial medicines, including Ciprofloxacin Viatris, 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**. 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.

Talk to your doctor or pharmacist before taking Ciprofloxacin Viatris if you:

- have ever had kidney problems, because your treatment may need to be adjusted
- suffer from epilepsy (fits) or other neurological conditions that predispose you to fits
- have a history of tendon problems during previous treatment with quinolone antibiotics such as ciprofloxacin
- have diabetes
- have myasthenia gravis (a type of muscle weakness) because symptoms can be exacerbated
- 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
- have heart problems. Caution should be taken when using ciprofloxacin, if you were born with or have family history of prolonged QT interval (seen on ECG, electrical recording of the heart), have salt imbalance in the blood (especially low level of potassium or magnesium in the blood), have a very slow heart rhythm (called 'bradycardia'), have a weak heart (heart failure), have a history of heart attack (myocardial infarction), you are female or elderly or you are taking other medicines that result in abnormal ECG changes (see section 2 'Other medicines and Ciprofloxacin Viatris').
- 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, Behçet's disease, high blood pressure, or known atherosclerosis, rheumatoid arthritis (a disease of the joints) or endocarditis (an infection of the heart).

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

When taking this medicine

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

- **Prolonged, disabling and potentially irreversible serious side effects**
Fluoroquinolone/quinolone antibacterial medicines, including Ciprofloxacin Viatris 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 Ciprofloxacin Viatris, **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.
- **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, chest pain, shortness of breath, feeling dizzy, sick or faint, or experiencing dizziness when standing up. **If this happens, stop taking Ciprofloxacin Viatris and contact your doctor or medical emergencies immediately.**
- **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 Ciprofloxacin Viatris therapy. At the first sign of pain or inflammation of a tendon (for example in your ankle, wrist, elbow, shoulder or knee), stop taking Ciprofloxacin Viatris, **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 Ciprofloxacin Viatris and contact your doctor immediately.
- You may experience **psychiatric reactions** the first time you take Ciprofloxacin Viatris. If you suffer from **depression** or **psychosis**, your symptoms may become worse under treatment with Ciprofloxacin Viatris. In rare cases, depression or psychosis can progress to suicidal thoughts and self-injurious behaviors such as suicide attempts or completed suicide (see section 4: Possible side

effects). If depression, psychosis, suicide-related thoughts or behaviour occur, 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 **Ciprofloxacin Viatris** and **inform your doctor immediately** in order to prevent the development of potentially irreversible condition.
- **Diarrhoea** may develop while you are taking antibiotics, including **Ciprofloxacin Viatris**, 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 **Ciprofloxacin Viatris** 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 **Ciprofloxacin Viatris**. Avoid exposure to strong sunlight, or artificial UV light such as sunbeds.
- Tell the doctor or laboratory staff that you are taking **Ciprofloxacin Viatris** 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.
- **Ciprofloxacin Viatris** may cause **liver damage**. If you notice any symptoms such as loss of appetite, jaundice (yellowing of the skin and whites of the eyes), dark urine, itching, or tenderness of the stomach, stop taking **Ciprofloxacin Viatris** and contact your doctor immediately.
- 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.

Ciprofloxacin Viatris 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 **Ciprofloxacin Viatris**

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

- **Do not take **Ciprofloxacin Viatris** together with tizanidine** (for muscle spasticity in multiple sclerosis or spinal injury or disease) because this may cause side effects such as low blood pressure and sleepiness (see Section 2 ‘Do not take **Ciprofloxacin Viatris**’).

You **must** tell your doctor if you are taking 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.

The following medicines are known to interact with **Ciprofloxacin Viatris** in your body. Taking **Ciprofloxacin Viatris** together with these medicines can influence the therapeutic effect of those medicines. It can also increase the chance of you getting side effects.

Tell your doctor if you are taking:

- Vitamin K antagonists (e.g. warfarin, acenocoumarol, phenprocoumon or fluindione) 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)
- olanzapine (an antipsychotic)
- clozapine (an antipsychotic)
- ropinirole (for Parkinson's disease)
- phenytoin (for epilepsy)
- metoclopramide (for nausea and vomiting)
- ciclosporin (for skin conditions, rheumatoid arthritis and in organ transplantation)

Ciprofloxacin Viatris may **increase** the levels of the following medicines in your blood and your doctor may need to adjust your dose. Tell your doctor if you are taking or wish to take:

- pentoxifylline (for circulatory disorders)
- caffeine
- duloxetine (for depression, anxiety, pain (diabetic nerve damage) or incontinence)
- lidocaine given as an injection (for heart conditions or an anaesthetic often used in surgical procedures)
- sildenafil (for impotence)
- agomelatine
- zolpidem

Some medicines **reduce** the effect of **Ciprofloxacin Viatris**. Tell your doctor if you are taking or wish to take:

- antacids (for indigestion)
- omeprazole (for gastric reflux often known as heartburn, stomach or intestinal ulcers)
- mineral supplements
- sucralfate (for stomach ulcers)
- medicines used to bind phosphate and reduce phosphate levels in the blood (e.g. sevelamer or lanthanum carbonate)
- medicines or supplements containing calcium, magnesium, aluminium or iron
- didanosine (used to treat HIV infection)

If these medicines must be taken, take **Ciprofloxacin Viatris** about two hours before or no sooner than four hours after them.

Ciprofloxacin Viatris with food and drink

Any calcium taken as part of a meal, including dairy products and drinks rich in calcium (such as milk or yoghurt) or fortified fruit-juices (e.g., orange juice containing added calcium), will not significantly affect the absorption of this medicine.

However, ciprofloxacin 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, ciprofloxacin 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 and breast feeding

Pregnancy

It is preferable to avoid the use of **Ciprofloxacin Viatris** during pregnancy. Tell your doctor if you are pregnant, think you may be pregnant or are planning to have a baby.

Breast-feeding

Do not take **Ciprofloxacin Viatris** during breast feeding because ciprofloxacin is passed into breast milk and can be harmful for your baby.

Driving and using machines

Ciprofloxacin Viatris may make you feel dizzy, less alert and affect your reaction time. Therefore, make sure you know how you react to **Ciprofloxacin Viatris** before driving a vehicle or operating machinery. If in doubt, talk to your doctor or pharmacist.

3. How to take **Ciprofloxacin Viatris**

Your doctor will explain to you exactly how much **Ciprofloxacin Viatris** 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 have 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 **Ciprofloxacin Viatris**.

Route and method of administration

- For oral use. Swallow the tablets with plenty of fluid. **Do not** chew the tablets because they do not taste nice.
- **Ciprofloxacin Viatris** 250 mg, 500 mg and 750 mg tablets have a score line. The score line is only there to help you break the tablet if you have difficulty swallowing the tablet whole.
- Do not crush the tablets. If you are not able to swallow the tablet, please inform your doctor, so that he could prescribe another formulation more suitable for you.
- Do try to take the tablets at around the same time every day.
- You can take the tablets at mealtimes or between meals.

You can take ciprofloxacin tablets during meals containing dairy products (such as milk or yoghurt) or with drinks rich in calcium (e.g. calcium-fortified orange juice). However, **do not** take **Ciprofloxacin Viatris** tablets 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.

Ciprofloxacin tablets should be taken one to two hours before or no sooner than four hours after dairy products drinks rich in calcium taken alone separately to meals.

Remember to drink plenty of fluids while you are taking **Ciprofloxacin Viatris**.

If you take more **Ciprofloxacin Viatris** than you should

If you take more tablets than you should, get medical help **immediately**. Take the remaining tablets and the container with you to show the doctor.

The following effects may be observed: dizziness, tremor, headache, tiredness, fits, seeing, feeling or hearing things that are not there (hallucinations), confusion, abdominal pain, liver problems, kidney problems, crystals or blood in the urine.

If you forget to take Ciprofloxacin Viatris

Take the normal dose as soon as possible, if it is 6 hours or more until your next scheduled dose and then continue as prescribed. However, if it is less than 6 hours until 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 Ciprofloxacin Viatris

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.

Stop taking Ciprofloxacin Viatris and contact your doctor immediately if you notice any of the following serious side effects:

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

- severe, sudden allergic reaction (see section 2 'While taking Ciprofloxacin Viatris') with symptoms such as:
 - rash, itchy skin, hives, tightness in the chest, feeling dizzy, sick or faint or experiencing dizziness when standing up (an anaphylactic reaction/shock)
 - rapid swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing (angioedema)
- muscle pain and/or weakness, inflammation of the joints and joint pain, increased muscle tone and cramping, inflammation of the tendons or tendon rupture, particularly affecting the large tendon at the back of the ankle (Achilles tendon) (see Section 2 'While taking Ciprofloxacin Viatris')
- increased number of infections, causing fever, severe chills, sore throat or mouth ulcers (due to decreased number of white blood cells in the blood) (see Section 2 'While taking Ciprofloxacin Viatris')

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

- serious skin reactions, such as
 - a widespread rash with blisters around the mouth, nose, eyes, genitals or body
 - pus-filled blisters and skin rash
 - skin rash which may blister and has central dark spots surrounded by a paler area with darker ring around the edge
 - a widespread rash with extensive peeling of the skin

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 'While taking Ciprofloxacin Viatris')
- abnormal heart rhythm (seen on ECG) (see Section 2 'Warnings and precautions')
- chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome
- an allergic reaction with symptoms that include rash, fever, swollen glands and abnormal blood test results (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS))

- loss of consciousness due to severe decrease in blood sugar levels (hypoglycaemic coma). See section 2.

Other side effects may include:

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

- feeling sick (nausea), diarrhoea
- joint pain in children

Uncommon (may affect up to 1 in 100 people):

- fungal superinfections
- increased number of white blood cells (eosinophilia, leukocytosis)
- decreased appetite
- hyperactivity or agitation
- headache, dizziness, sleeping problems, 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 (e.g. back pain, chest pain, pain in extremities), unusual weakness (asthenia), fever
- increase in a certain substance in the blood (alkaline phosphatase)

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

- severe or persistent diarrhoea that may contain blood or mucous (colitis) (see Section 2 ‘While taking Ciprofloxacin Viatris’)
- reduced number of red blood cells which causes weakness or breathlessness and may make the skin pale (anaemia)
- unexpected bruising or bleeding for longer than normal (thrombocytopenia)
- increased number of blood platelets (thrombocytaemia)
- increased blood sugar (hyperglycaemia)
- decreased blood sugar (hypoglycaemia – see section 2 ‘Warnings and precautions’ and ‘While taking Ciprofloxacin Viatris’)
- 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
- seizures, fits or convulsions (including prolonged or repeated fits without any recovery in between) (see Section 2 ‘While taking Ciprofloxacin Viatris’)
- tingling or numbness of the hands or feet, pins and needles (paraesthesia), unusual sensitivity to stimuli of the senses (dysaesthesia), decreased sense of touch, sensation or skin sensitivity (hypoaesthesia), tremors
- giddiness, spinning sensation (vertigo)
- eyesight problems such as difficulties telling colours apart, blurred or double vision (see section 2 ‘While taking Ciprofloxacin Viatris’)
- buzzing, hissing, whistling, ringing or other persistent noise in the ears (tinnitus), loss of hearing, impaired hearing
- rapid heartbeat (tachycardia)
- expansion of blood vessels (vasodilation), low blood pressure, fainting
- shortness of breath, including asthmatic symptoms
- liver disease, including inflammation of the liver (hepatitis), with symptoms such as loss of appetite, yellowing of the skin and whites of the eyes, dark urine, itching or tenderness of the

stomach. Very rarely, death of liver cells (liver necrosis) which may lead to liver failure (see Section 2 'While taking Ciprofloxacin Viatriis')

- sensitivity to light (see Section 2 'While taking Ciprofloxacin Viatriis')
- kidney failure (symptoms like feeling sick (nausea), loss of appetite, weakness, little or no urine), blood or crystals in the urine (see Section 2 'While taking Ciprofloxacin Viatriis'), 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):

- other allergic reactions with symptoms that include fever, swelling, skin rash and enlargement of the lymph nodes (serum sickness)
- damaged red blood cells, which causes weakness or breathlessness with yellowing of the skin and whites of the eyes
- inflammation of the pancreas (pancreatitis) which causes severe upper stomach pain, often with feeling sick (nausea) and being sick (vomiting)
- migraine, changes in coordination, unsteady walk (gait disturbance), changes in sense of smell (olfactory disorders), increased pressure on the brain (intracranial pressure or pseudotumour cerebri)
- inflammation of the wall of the blood vessels (vasculitis)
- small, pin-point bleeding under the skin (petechiae)
- red-purple swellings on the shins, thighs and less commonly the arms. Joint, muscle pains and fever may also occur (erythema nodosum)
- worsening of the symptoms of myasthenia gravis (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)

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

- feeling highly excited (mania) or feeling great optimism and overactivity (hypomania)
- increased blood clotting time in patients treated with Vitamin K antagonist (used for preventing blood clots, e.g. warfarin)
- alteration of the heart rhythm (called 'prolongation of QT interval' and seen on ECG) (see Section 2 'Warnings and precautions')
- syndrome associated with impaired water excretion and low levels of sodium (SIADH).

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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system](#) listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store **Ciprofloxacin Viatris**

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

Do not use this medicine after the expiry date, which is stated on the blister or carton after 'EXP': The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 protect the environment.

6. Contents of the pack and other information

What **Ciprofloxacin Viatris** contains

The active substance is ciprofloxacin. Each tablet contains 100 mg, 250 mg, 500 mg or 750 mg of ciprofloxacin (as ciprofloxacin hydrochloride).

The other ingredients of the tablets are cellulose microcrystalline, maize starch, crospovidone, starch pregelatinised, silica colloidal anhydrous and magnesium stearate. The film-coating contains hypromellose, titanium dioxide (E171), polydextrose, glycerol triacetate and macrogol.

What **Ciprofloxacin Viatris** looks like and contents of the pack

Ciprofloxacin Viatris 100 mg tablets are white, round film-coated tablets marked 'CF' on one side and 'G' on the other side.

Ciprofloxacin Viatris 250 mg are white, round film-coated tablets marked 'CF scoreline 250' on one side and 'G' on the other side.

Ciprofloxacin Viatris 500 mg are white capsule-shaped film-coated tablets and marked 'CF scoreline 500' on one side and 'G' on the other.

Ciprofloxacin Viatris 750 mg are white capsule-shaped film-coated tablets and marked 'CF scoreline 750' on one side and 'G' on the other.

Ciprofloxacin Viatris 100 mg tablets are available in blister packs of 6, 10, 12, 14, 16, 20, 100 and 120 tablets.

Ciprofloxacin Viatris 250 mg, 500 mg, 750 mg tablets are available in blister packs of 1, 6, 8, 10, 12, 14, 16, 20, 100 and 120 tablets.

Ciprofloxacin Viatris tablets are available in bottles of 6, 10, 12, 14, 16, 20, 100 and 120 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: [To be completed nationally]

Manufacturer: [To be completed nationally]

This medicine is authorised in the Member States of the European Economic Area under the following names:

Belgium	-	Ciprofloxacin Viatri
Italy	-	Ciprofloxacin Mylan Generics
Luxembourg	-	Ciprofloxacin Viatri
Netherlands	-	Ciprofloxacin Viatri
Portugal	-	Ciprofloxacin Mylan
Sweden	-	Ciprofloxacin Viatri

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[To be completed nationally]

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 which may lead to some antibiotic treatments becoming 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 follow the prescribed:

- 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; as it may not be appropriate for her/his illness.
- 5 - After completion of treatment, return all unused drugs to your pharmacist to ensure they will be disposed of correctly.