

CIPROFLOXACIN TEVA 250 mg  
FILM-COATED TABLETS  
CIPROFLOXACIN TEVA 500 mg  
FILM-COATED TABLETS  
CIPROFLOXACIN TEVA 750 mg  
FILM-COATED TABLETS

Ciprofloxacin

PATIENT LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

IN THIS LEAFLET:

- What Ciprofloxacin Teva is and what it is used for
- Before you take Ciprofloxacin Teva
- How to take Ciprofloxacin Teva
- Possible side effects
- How to store Ciprofloxacin Teva
- Further information

1 WHAT CIPROFLOXACIN TEVA IS AND WHAT IT IS USED FOR

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

Adults

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

- respiratory tract infections
- long lasting or recurring ear or sinus infections
- urinary tract infections
- infections of the testicles
- genital organ infections in women
- gastro-intestinal tract infections and intra-abdominal infections
- skin and soft tissue infections
- bone and joint infections
- to treat infections in patients with a very low white blood cell count (neutropenia)
- to prevent infections in patients with a very low white blood cell count (neutropenia)
- to prevent infections due to the bacterium *Neisseria meningitidis*
- anthrax inhalation exposure

If you have a severe infection or one that is caused by more than one type of bacterium, you may be given additional antibiotic treatment in addition to Ciprofloxacin Teva.

Children and adolescents

Ciprofloxacin Teva 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

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

2 BEFORE YOU TAKE CIPROFLOXACIN TEVA

Do NOT take Ciprofloxacin Teva if you are

- allergic (hypersensitive) to the active substance, to other quinolone drugs or to any of the other ingredients of Ciprofloxacin Teva (see section 6)
- taking tizanidine (see Section 2: Taking other medicines)

Take special care with Ciprofloxacin Teva

Before taking Ciprofloxacin Teva

Heart Problems

Caution should be taken when using this kind of medicine, if you were born with or have a family history of prolonged QT interval (seen on ECG, electrical recording of the heart), have salt imbalance in the blood (especially low level 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 *Taking other medicines*).

Tell your doctor if you:

- 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 Ciprofloxacin Teva
- have myasthenia gravis (a type of muscle weakness)

While taking Ciprofloxacin Teva

Tell your doctor immediately, if any of the following occurs **while taking Ciprofloxacin Teva**. Your doctor will decide whether treatment with Ciprofloxacin Teva 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 Ciprofloxacin Teva 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 Ciprofloxacin Teva therapy. At the first sign of any pain or inflammation stop taking Ciprofloxacin Teva 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 Teva and contact your doctor immediately.
- You may experience **psychiatric reactions** the first time you take Ciprofloxacin Teva. If you suffer from **depression** or **psychosis**, your symptoms may become worse under treatment with Ciprofloxacin Teva. In rare cases, depression or psychosis can progress to thoughts of suicide, suicide attempts, or completed suicide. If this happens, stop taking Ciprofloxacin Teva and contact your doctor immediately.

- You may experience symptoms of neuropathy such as pain, burning, tingling, numbness and/or weakness. If this happens, stop taking Ciprofloxacin Teva and contact your doctor immediately.
- Diarrhoea** may develop while you are taking antibiotics, including Ciprofloxacin Teva, 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 Teva immediately, as this can be life-threatening. Do not take medicines that stop or slow down bowel movements and contact your doctor.
- Tell the doctor or laboratory staff that you are taking Ciprofloxacin Teva 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 Teva 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 Ciprofloxacin Teva and contact your doctor immediately.
- Ciprofloxacin Teva may cause a reduction in the number of white blood cells and your **resistance to infection may be decreased**. If you experience an infection with symptoms such as fever and serious deterioration of your general condition, or fever with local infection symptoms such as sore throat/pharynx/mouth or urinary problems you should see your doctor immediately. A blood test will be taken to check possible reduction of white blood cells (agranulocytosis). It is important to inform your doctor about your medicine.
- Tell your doctor if you or a member of your family is known to have a deficiency in glucose-6-phosphate dehydrogenase (G6PD), since you may experience a risk of anaemia with ciprofloxacin.
- Your skin becomes more **sensitive to sunlight or ultraviolet (UV) light** when taking Ciprofloxacin Teva. Avoid exposure to strong sunlight, or artificial UV light such as sunbeds.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including any that you obtained without a prescription. 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, aminodarone, sotalol, defetilide, ibutilide), tricyclic antidepressants, some antimicrobials (that belong to the group of macrolides), some antipsychotics.

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

The following medicines are known to interact with Ciprofloxacin Teva in your body. Taking Ciprofloxacin Teva 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) or other oral anti-coagulants (to thin the blood)
- probenecid (for gout)
- metoclopramide (for nausea/vomiting)
- methotrexate (for certain types of cancer, psoriasis, rheumatoid arthritis)
- theophylline (for breathing problems)
- tizanidine (for muscle spasticity in multiple sclerosis)
- ciclosporin (for prevention of transplant rejection)
- glibenclamide (for treating diabetes)
- ciclosporin (for prevention of transplant rejection)
- glibenclamide (for treating diabetes)
- clozapine (an antipsychotic)
- olanzapine (an antipsychotic)
- ropinirole (for Parkinson's disease)
- phenytoin (for epilepsy)

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

- pentoxifylline (for circulatory disorders)
- caffeine
- duloxetine (for treating depression)
- lidocaine (for local anaesthesia)
- sildenafil (for erectile dysfunction)

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

- antacids
- omeprazole (for treating stomach ulcers)
- mineral supplements
- sucralfate
- a polymeric phosphate binder (e.g. sevelamer)
- medicines or supplements containing calcium, magnesium, aluminium or iron

If these preparations are essential, take Ciprofloxacin Teva about two hours before or no sooner than four hours after them.

Taking Ciprofloxacin Teva with food and drink

Unless you take Ciprofloxacin Teva during meals, do not eat or drink any dairy products (such as milk or yoghurt) or drinks with added calcium when you take the tablets, as they may affect the absorption of the active substance.

Pregnancy and breast-feeding

It is preferable to avoid the use of Ciprofloxacin Teva during pregnancy. Tell your doctor if you are planning to get pregnant.

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

Driving and using machines

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

3 HOW TO TAKE CIPROFLOXACIN TEVA

Dosage

Your doctor will explain to you exactly how much Ciprofloxacin Teva 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.

Duration of treatment

The treatment usually lasts from 5 to 21 days, but may take longer for severe infections.

Method of administration

Take the tablets exactly as your doctor has told you. Ask your doctor or pharmacist if you are not sure how many tablets to take and how to take Ciprofloxacin Teva.

- Swallow the tablets with plenty of fluid. Do not chew the tablets because they do not taste nice.
- Do try to take the tablets at around the same time every day.
- 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 Ciprofloxacin Teva tablets with dairy products such as milk or yoghurt or with fortified fruit-juices (e.g. calcium-fortified orange juice).



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Supplier Instructions Artwork, text and content must NOT be altered. The only exceptions to this are: bleeds, chokes, spreads or other adjustments required for print reproduction purposes only. If you have any difficulties please contact the Teva Artwork Team. We must receive a copy of the 3rd Party Vendors Proof before final approval can be made.

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

**If you take more Ciprofloxacin Teva 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 Ciprofloxacin Teva**  
Take the normal dose as soon as possible and then continue as prescribed. However, if it is almost time for your next dose, do not take the missed dose and continue as usual. Do not take a double dose to make up for a forgotten dose. Be sure to complete your course of treatment.

**If you stop taking Ciprofloxacin Teva**  
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 product, ask your doctor or pharmacist.

#### 4 POSSIBLE SIDE EFFECTS

Like all medicines, Ciprofloxacin Teva can cause side effects, although not everybody gets them.

A few people may develop very serious side effects. If you experience any of the following symptoms, **tell your doctor immediately**:

- swelling of the face, hands, lips, tongue or throat, difficulty swallowing or breathing
- severe skin rash with blistering or bleeding of the lips, skin, nose, mouth, eyes and genitals
- severe diarrhoea, sometimes with blood or mucus
- inflammation of the tendons or a ruptured tendon
- fits or seizures
- unusual feelings of pain, burning, tingling, numbness or muscle weakness
- yellowing of the skin or eyes, dark urine, tenderness in the abdomen or weight loss.

The following side effects have been reported at the approximate frequencies shown:

**Common side effects** (between 1 and 10 in every 100 people are likely to get these):

- nausea, diarrhoea
- joint pains in children

**Uncommon side effects** (between 1 and 10 in every 1,000 people are likely to get these):

- fungal superinfections
- a high concentration of eosinophils, a type of white blood cell
- loss of appetite (anorexia)
- hyperactivity or agitation
- headache, dizziness, sleeping problems, or taste disorders
- vomiting, abdominal pain, digestive problems such as stomach upset (indigestion/heartburn), or wind
- increased amounts of certain substances in the blood (transaminases and/or bilirubin)
- rash, itching, or hives
- joint pain in adults
- poor kidney function
- pains in your muscles and bones, feeling unwell (asthenia), or fever
- increase in blood alkaline phosphatase (a certain substance in the blood)

**Rare side effects** (between 1 and 10 in every 10,000 people are likely to get these):

- inflammation of the bowel (colitis) linked to antibiotic use (can be fatal in very rare cases) (see Section 2: Take special care with Ciprofloxacin Teva)
- changes to the blood count (leukopenia, leukocytosis, neutropenia, anaemia), increased or decreased amounts of a blood clotting factor (thrombocytes)
- allergic reaction, swelling (oedema), or rapid swelling of the skin and mucous membranes (angio-oedema)
- increased blood sugar (hyperglycaemia)
- confusion, disorientation, anxiety reactions, strange dreams, depression (potentially culminating in suicidal thoughts or suicide attempts and completed suicide), or hallucinations
- pins and needles, unusual sensitivity to stimuli of the senses, decreased skin sensitivity, tremors, seizures (see Section 2: Take special care with Ciprofloxacin Teva), or giddiness
- eyesight problems incl. double vision
- 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: Take special care with Ciprofloxacin Teva)
- muscle pain, inflammation of the joints, increased muscle tone, or cramp
- kidney failure, blood or crystals in the urine (see Section 2: Take special care with Ciprofloxacin Teva), urinary tract inflammation
- fluid retention or excessive sweating
- increased levels of the enzyme amylase in the blood

**Very rare side effects** (less than 1 in every 10,000 people are likely to get these):

- a special type of reduced red blood cell count (haemolytic anaemia); a dangerous drop in a type of white blood cells (agranulocytosis ); a drop in the number of red and white blood cells and platelets (pancytopenia), which may be fatal; and bone marrow depression, which may also be fatal (see Section 2: Take special care with Ciprofloxacin Teva)
- severe allergic reactions (anaphylactic reaction or anaphylactic shock, which can be fatal - serum sickness) (see Section 2: Take special care with Ciprofloxacin Teva)
- mental disturbances (psychotic reactions, potentially culminating in suicidal thoughts or suicide attempts and completed suicide) (see Section 2: Take special care with Ciprofloxacin Teva)
- migraine, disturbed coordination, unsteady walk (gait disturbance), disorder of sense of smell (olfactory disorders), pressure on the brain (intracranial pressure)
- visual colour distortions
- inflammation of the wall of the blood vessels (vasculitis)
- pancreatitis
- death of liver cells (liver necrosis) very rarely leading to life-threatening liver failure
- small, pin-point bleeding under the skin (petechiae); various skin eruptions or rashes (for example, the potentially fatal Stevens-Johnson syndrome or toxic epidermal necrolysis)
- muscle weakness, tendon inflammation, tendon rupture – especially of the large tendon at the back of the ankle (Achilles tendon) (see Section 2: Take special care with Ciprofloxacin Teva); worsening of the symptoms of myasthenia gravis (see Section 2: Take special care with Ciprofloxacin Teva)

**Frequency not known** (cannot be estimated from the available data)

- troubles associated with the nervous system such as pain, burning, tingling, numbness and/or weakness in extremities

- abnormal fast heart rhythm, life-threatening irregular heart rhythm, alteration of the heart rhythm (called ‘prolongation of QT interval’, seen on ECG, electrical activity of the heart).
- increase in the blood coagulation parameters (in patients treated with vitamin K antagonists)
- skin disorder characterised by the rapid appearance of areas of red skin studded with small blisters filled with white/yellow fluid (pustular rash)

*If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.*

#### 5 HOW TO STORE CIPROFLOXACIN TEVA

**Keep out of the reach and sight of children.**

**Expiry date**  
Do not use Ciprofloxacin Teva after the expiry date which is stated on the packaging. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 FURTHER INFORMATION

**What Ciprofloxacin Teva contains**

- The active substance is ciprofloxacin.
- Each 250 mg film-coated tablet contains 250 mg ciprofloxacin as ciprofloxacin hydrochloride.
- Each 500 mg film-coated tablet contains 500 mg ciprofloxacin as ciprofloxacin hydrochloride.
- Each 750 mg film-coated tablet contains 750 mg ciprofloxacin as ciprofloxacin hydrochloride.
- The other ingredients are microcrystalline cellulose, povidone, croscarmellose sodium, colloidal silica and magnesium stearate. The coating contains hypromellose, macrogol 400 and the colour titanium dioxide (E171).

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

- 250 mg: White, biconvex, round film-coated tablets, debossed “CIP 250” and breakline on one side and plain on the other. The tablet can be divided into equal halves. The product is available in pack sizes\* of 8, 10, 12, 16, 20, 30, 50, 100 and 160 tablets.
- 500 mg: White, capsule shaped film-coated tablets, debossed “CIP 500” and breakline on one side and plain on the other. The tablet can be divided into equal halves. The product is available in pack sizes\* of 6, 8, 10, 12, 16, 20, 30, 50, 100, 120 and 160 tablets.
- 750 mg: White, capsule shaped film-coated tablets, debossed “CIP 750” on one side and plain on the other. The product is available in pack sizes\* of 8, 10, 12, 16, 20, 30, 50, 100 and 160 tablets.

\* Not all pack sizes may be marketed.

**This medicinal product is authorised in the Member States under the following names:**

AT:	Ciprofloxacin Teva-TEVA 100/250/500/750 mg Filmtabletten
BE:	Ciprofloxacin Tevae TEVA 100/250/500 mg filmomhulde tabletten
CZ:	Ciprofloxacin Teva-Teva 250/500/750 mg
DE:	Gyracip N® 100/250/500/750 mg Filmtabletten
DK:	Ciprofloxacin Teva TEVA
EL:	Ciprofloxacin Tevae Teva 100/250/500/750 mg Επικαλυμμένα με λεπτό υμένιο δισκία
FI:	Ciprofloxacin Teva TEVA 100/250/500/750 mg tabletti, kalvopäällysteinen
HU:	Ciprofloxacin Teva-Human 100/250/500/750 mg filmtabletta
IE:	Ciprofloxacin Teva Teva 250/500/750 mg Film-coated Tablets
IT:	Ciprofloxacin Tevaa Ranbaxy 250/500/750 mg compresse rivestite con film
LU:	Ciprofloxacin Tevae TEVA 100/250/500/750 mg comprimés pelliculés
NL:	Ciprofloxacin Tevae 100/250/500/750 mg PCH, filmomhulde tabletten
NO:	Ciprofloxacin Teva TEVA 100/250/500/750 mg tabletter, filmdrasjerte
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PT:	Ciprofloxacin Tevaa Teva 250/500/750 mg Comprimidos
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UK:	Ciprofloxacin Teva 100/250/500/750 mg Film-Coated Tablets

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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.



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