



**SPECTRUM® 250 & 500 mg B/10 & B/20**  
**SPECTRUM® 750 mg B/10**  
Film-coated tablets  
(Ciprofloxacin)

Read this entire leaflet carefully before you start taking this medicine. Keep this leaflet. You may need to read it again. If you have any other questions, or if there is something you don't understand ask your doctor or pharmacist. This medicine has been prescribed for you. Never give it to someone else. It may not be the right medicine for them even if their symptoms seem to be the same as yours. If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**1. COMPOSITION OF MEDICINAL PRODUCT**

**Drug substance:** Ciprofloxacin 250, 500 ou 750 mg

For 1 film-coated tablet

The exact amount is indicated on the box.

**Common excipients:** Croscarmellose sodium, Microcrystalline cellulose, Povidone, Magnesium stearate, Colloidal silica, Hypromellose, Titanium dioxide, Talc, Propylene glycol, PEG 6000.

**2. PHARMACO-THERAPEUTIC CLASS**

Pharmacotherapeutic group: Fluoroquinolone - ATC code: J01MA02

SPECTRUM contains an active substance, ciprofloxacin.

**3. THERAPEUTIC INDICATIONS**

Ciprofloxacin is an antibiotic belonging to the fluoroquinolone family. It works by killing the bacteria responsible for infections. It is active only on certain specific strains of bacteria.

**→ Adults:**

SPECTRUM 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.

SPECTRUM may be used to treat infections in patients with a low white blood cell count (neutropenia) who have a fever that is suspected to be caused by a bacterium. If you have a severe infection or one that is caused by different types of bacteria, you may be given additional antibiotic treatment in addition to SPECTRUM.

**→ Children and adolescents**

SPECTRUM 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)

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

**4. DOSAGE AND ADMINISTRATION ROUTE**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if in doubt.

Your doctor will explain exactly how much SPECTRUM you need to take, how often and for how long. This will depend on the type of infection and its severity. Tell your doctor if you have kidney problems because the dose of medicine to take may need to be adapted.

The treatment usually lasts from 5 to 21 days but may be longer in case of severe infection. Always take the dose recommended by your doctor. Check with your doctor or pharmacist if you have any doubts about how many SPECTRUM to take or how to take them.

a. Swallow the tablets with a large amount of drink. Do not crush the tablets because they taste bad.

b. Try to take the tablets at around the same time each 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 SPECTRUM 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 SPECTRUM.

**5. CONTRE INDICATIONS**

Do not take SPECTRUM, film-coated tablets:

- If you are allergic to the active substance, to other quinolones or to any of the other ingredients of this medicine (see section 1)
- If you are taking tizanidine (see section 8).

**6. POSSIBLE SIDE EFFECTS**

**Description of side effects:**

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

**The most serious side effects that you can recognize yourself are listed in the section below.**

Stop taking SPECTRUM and contact your doctor immediately to consider another antibiotic treatment if you notice any of the serious side effects listed below.

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

• Seizures (see section 7)

• Muscle weakness (may affect up to 1 in 10,000 people)

• Severe and sudden allergic reaction manifested by symptoms such as tightness in the chest, dizziness, feeling of malaise or weakness, or dizziness when standing up (anaphylactic reaction, anaphylactic shock) (see section 7)

• Muscle weakness, inflammation of the tendons that can lead to tendon rupture, particularly of the large tendon located at the ankle (Achilles tendon) (see section 7)

• Severe skin rash that may be life-threatening usually in the form of blisters or ulcerations in the mouth, throat, nose, eyes and other mucous membranes such as genitals, and may progress to blistering or peeling all over the body (Stevens-Johnson syndrome, Lyell's syndrome)

**Not known frequency** (frequency cannot be estimated based on available data)

• Unusual sensations of pain, burning, tingling, numbness or muscle weakness in the extremities (neuropathy) (see section 7)

• An adverse reaction that causes rash, fever, internal organ inflammation, hematologic abnormalities, and systemic disease (drug-induced hypersensitivity syndrome with eosinophilia and systemic symptoms known as DRESS syndrome [Drug Reaction with Eosinophilia and Systemic Symptom], PEAG: Generalized Acute Exanthematous Pustulosis).

**Common side effects that have been observed during treatment with SPECTRUM are listed below according to their frequency of occurrence:**

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

- Nausea, diarrhea
- Pain in the joints and inflammation of the joints in the child.

**Uncommon side effects** (may affect up to 1 in 100 people)

- Joint pain in adults
- Fungal superinfections (due to fungi)
- A high concentration of a type of white blood cells (eosinophils)
- Decreased appetite
- Hypersensitivity, agitation
- Headaches, dizziness, sleeping problems, taste disorders
- Vomiting, abdominal pain, digestive problems such as stomach upset (indigestion / heartburn) or flatulence

- Increased amount of certain substances in the blood (transaminases and / or bilirubin)
- Rash, itching, hives
- Impairment of kidney function
- Pain in your muscles and bones, feeling unwell (asthenia), fever
- Increase of the level of a substance in the blood (alkaline phosphatase).

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

- Muscle pain, inflammation of the joints, increased muscle tone and cramps
- Inflammation of the bowel (colitis) linked to antibiotics use (can be fatal in very rare cases) (see section 7)

• Change in the number of certain white blood cells or red blood cells (leukopenia, leukocytosis, neutropenia, anemia), increase or decrease in amount of factors present in the blood used for blood coagulation (platelets)

- Allergic reaction, swelling (edema) or rapid swelling of the skin and mucous membranes (angioedema) (see section 7)
- Increased blood sugar levels (hyperglycaemia)
- Decreased blood sugar levels (hypoglycaemia) (see section 7)

• Confusion, disorientation, anxiety reactions, strange dreams, depression (which may lead to suicidal thoughts, suicide attempts or suicide) (see section 7), hallucinations

- Tingling sensation, unusual sensitivity to sensory stimuli, decreased skin sensitivity, tremors, vertigo
- Vision disorders, including double vision (see section 7)
- Tinnitus, trouble or loss of hearing
- Heartbeat accelerated (tachycardia)
- Widening of blood vessels (vasodilatation), low blood pressure, fainting
- Shortness of breath, including asthmatic symptoms
- Liver disorders, jaundice (cholestatic jaundice), hepatitis

• Sensitivity to light (see section 7)

• Kidney failure, presence of blood or crystals in the urine, urinary tract inflammation

• Water retention, excessive sweating

• Increase in the concentration in the blood of an enzyme derived from the pancreas (amylase).

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

• Particular type of decrease in the number of red blood cells in the blood (haemolytic anemia), very significant decrease in the number of certain white blood cells (agranulocytosis) (see section 7), decrease in the number of red blood cells, white blood cells and platelets (pancytopenia) that can be fatal, depletion of bone marrow in blood cells (bone marrow suppression) can also be fatal

• Allergic reaction known as serum sickness reaction (see section 7)

• Psychiatric disorders (psychotic reactions that may lead to suicidal thoughts, suicide attempts or suicide) (see section 7)

• Migraine, coordination disorders, unsteady walk (gait disorders), small disorders (dystonia disorders), pressure on the brain (intracranial hypertension and cerebral pseudotumor)

• Color vision disorders

• Inflammation of the wall of the blood vessels (vasculitis)

• Inflammation of the pancreas (pancreatitis)

• Death of liver cells (liver necrosis) very rarely leading to life-threatening liver failure (see section 7)

• Small bleeding in the form of red dots under the skin (petechiae), various rashes

• Worsening of symptoms of myasthenia gravis (see section 7)

**Frequency not known** (frequency cannot be estimated based on available data)

• Feeling of being very excited (mania) or feeling of great optimism with hyperactivity (hypomania)

• Abnormally fast heartbeat, irregular heartbeat that puts your life at risk, altered heart rhythm (called "QT prolongation", see on ECG, recording of electrical heart pattern)

• Influence on blood clotting (in patients treated with vitamin K antagonists).

**Reporting of side effects**

The reporting of suspected side effects after approval of the drug is important. It allows continuous monitoring of the benefit / risk ratio of the drug.

**7. SPECIAL WARNINGS AND PRECAUTIONS FOR USE**

**→ Talk to your doctor before taking SPECTRUM**

• Have ever had kidney problems because your treatment may need to be adjusted.

• You have epilepsy or any other neurological disease.

• You have already had tendon problems with antibiotics from the same family as SPECTRUM.

• If you have diabetes because you may be at risk of hypoglycaemia with ciprofloxacin;

• If you have myasthenia gravis (a rare condition that causes muscle weakness) because symptoms can be exacerbated

• If you have been diagnosed with an enlargement or "bulge" of a large blood vessel (aortic aneurysm or large vessel peripheral aneurysms).

• 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 heart problems. Ciprofloxacin should be used with caution if you were born or have a family history of QT prolongation interval (seen on ECG, electrical recording of the heart), if you have an electrolyte imbalance in the blood (including a low level of potassium or magnesium in the blood), if you have a very slow heart rhythm (called "bradycardia"), if you have a weak heart (heart failure), if you have ever had a heart attack (myocardial infarction), if you are a female or elderly person, or if you are taking other medicines that result in abnormal ECG changes (see section 8).

• If you or a member of your family is known to have a deficiency in glucose-6-phosphate dehydrogenase (G6PD) because taking ciprofloxacin may cause anaemia.

For the treatment of certain infections of the genitals, your doctor may prescribe another antibiotic in combination with SPECTRUM. If no improvement in symptoms is observed after 3 days of treatment, please consult your doctor.

**→ While taking SPECTRUM**

Tell your doctor immediately if any of the following conditions occur while taking SPECTRUM. Your doctor will decide whether treatment with SPECTRUM needs to be stopped.

• **Severe and sudden allergic reaction** (an anaphylactic reaction / shock, Quincke's edema). 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, nausea or faint, or experiencing dizziness when standing up. **If this happens, stop taking SPECTRUM, film-coated tablets as your life may be in danger, and contact your doctor immediately.**

• Pain and swelling in the joints and tendonitis may occur occasionally, especially if you are elderly and if you are also being treated with corticosteroids. Inflammation and rupture of the tendons can occur from the first 48 hours of treatment and up to several months after the cessation of SPECTRUM therapy. At the slightest sign of pain or inflammation of the joints or tendons, stop taking SPECTRUM and rest the affected limb. Avoid unnecessary exercise, as this might increase the risk of tendon rupture.

• If you experience sudden and intense pain in the abdomen, chest or back, go to the hospital emergency department immediately.

• If you suffer from epilepsy or other neurological disease such as cerebral ischemia or stroke, neurological side effects (seizures) may occur. If this happens, stop SPECTRUM and contact your doctor immediately.

• You may have symptoms suggestive of neuropathy, such as pain, burning, tingling, numbness, and / or muscle weakness. If such symptoms occur, stop SPECTRUM and contact your doctor immediately.

**Psychiatric reactions** may occur from the first dose of SPECTRUM. If you suffer from depression or psychosis, your symptoms may worsen during treatment with SPECTRUM. In rare cases, depression or psychosis can progress to suicidal thoughts, suicide attempts or suicide. If such reactions occur, contact your doctor immediately.

• Cases of hypoglycaemia have been reported most often in diabetic patients, mainly in the elderly population. If this undesirable effect occurs, contact your doctor immediately.

• Diarrhea may develop when taking antibiotics, including SPECTRUM, or even several weeks after the end of treatment. If diarrhea becomes severe or persistent, or if you notice that your stool contains blood or mucus, stop taking SPECTRUM immediately, as this can be life-threatening. Do not take medicines to block or slow down the intestinal transit and contact your doctor.

• If your eyesight deteriorates or you feel any effect on the eyes, consult an eye doctor immediately.

• Your skin becomes more sensitive to the sunlight or ultraviolet light (UV) when taking SPECTRUM. Avoid prolonged exposure to sunlight or artificial UV light such as sunbeds.

• Tell the doctor or the laboratory staff that you are taking SPECTRUM if you have to provide a blood or urine sample.

• If you have kidney problems, tell your doctor because the dose of SPECTRUM may need to be adjusted.

• SPECTRUM may cause liver damage. If you notice any symptoms such as loss of appetite, jaundice, dark urine, itching, or tenderness of the stomach, stop taking SPECTRUM and contact your doctor immediately.

• SPECTRUM can cause a decrease in white blood cells in your blood and reduce your resistance to infections. If you have an infection with symptoms such as fever and a significant change in your general condition or a fever with symptoms of local infection such as sore throat / pharynx / mouth or urinary problems, should consult your doctor immediately. A blood test will be performed to look for a possible decrease in the rate of certain white blood cells (agranulocytosis). It is important to tell your doctor that you are taking this medicine.

**8- INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION**

**Interaction with other medicinal products**

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

**Do not take SPECTRUM, film-coated tablets together with tizanidine**, because this may cause side effects such as low blood pressure and sleepiness (see section 5).

The following medicines are known to interact with SPECTRUM. Taking SPECTRUM together with these medicines can influence the therapeutic effects of these medicines and it can also increase.

**Tell your doctor if you are taking:**

- Vitamin K antagonists (e.g. warfarin, acenocoumarol, phenprocoumon or fluindione) or other oral anticoagulants (intended to thin the blood)
- Probenecid (used to treat gout)
- Metohexalene (used for certain types of cancer, psoriasis, rheumatoid arthritis)
- Theophylline (used for breathing problems)
- Tizanidine (used for muscle spasticity problems related to multiple sclerosis)
- Olanzapine (an antipsychotic)
- Clozapine (used in some psychiatric diseases)
- Ropinirole (For Parkinson's disease)
- Phenytoin (For epilepsy)
- Metoprololam (used for nausea and vomiting)
- Clozapine (used for skin diseases, rheumatoid arthritis, and organ transplants)
- Other medicines that may affect your heart rate: medicines in the anti-arrhythmic group (e.g. quinidine, hydroquinidine, disopyramide, amiodaron, sotalol, dofetilide, ibutilide), tricyclic antidepressants, some antibiotics (which belong to the macrolide family), some antipsychotics.
- Zolpidem (used in sleep disorders).
- SPECTRUM may increase the levels of the following medicines in your blood: Pentoxifylline (for circulatory disorders)
- Caffeine.
- Duloxetine (used in depression, nerve damage related to diabetes or urinary incontinence)
- Lidocaine (used in heart disease or anesthetic use)
- Sildenafil (e.g. in erectile dysfunction)
- Agomelatine (used in depression).

Some medicines **reduce** the effects of SPECTRUM. Tell your doctor if you are taking or plan to take:

- Antacids
- Omeprazole
- Mineral supplements
- Sucralfate
- A polymeric phosphate binder (e.g. sevelamer or lanthanum carbonate).

Medicines or supplements containing calcium, magnesium, aluminum or iron.

If it is essential for you to take these medications, take SPECTRUM about two hours before or no sooner than four hours after them.

**Interactions with food and drinks:**

If you take SPECTRUM outside of meals, do not consume dairy products (eg milk or yogurts) or calcium-enriched beverages when taking ciprofloxacin tablets as dairy products may decrease the effect of the drug.

• Cases of hypoglycaemia have been reported most often in diabetic patients, mainly in the elderly population. If this undesirable effect occurs, contact your doctor immediately.

**9. USE IN CASE PREGNANCY AND BREAST-FEEDING**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. It is best to avoid using SPECTRUM during pregnancy.

Do not take SPECTRUM while breastfeeding as ciprofloxacin passes into breast milk and could affect your child's health.

Ask your doctor or pharmacist for advice before taking any medicine.

**10. THE POSSIBLE EFFECTS OF TREATMENT ON THE ABILITY TO DRIVE OR USE CERTAIN MACHINES**

SPECTRUM can lower your level of alertness. Neurological side effects may occur. Therefore, make sure you know how you react to SPECTRUM before driving or using machines. If in doubt, talk to your doctor.

**11. SYMPTOMS AND WHAT TO DO IN CASE OF OVERDOSE**

If you take more of this medicine than you should:

If you take more than the prescribed dose, consult your doctor immediately. If possible, take your tablets or the box with you to show the doctor.

**12. WHAT TO DO IN CASE OF OMISSION OF ONE OR MORE DOSES**

If you forget to take this medicine:

Take the missed dose as soon as possible, then continue treatment normally. However, if it is almost time to take the next dose, do not take the missed dose and continue treatment normally. Do not take a double dose to make up for the dose you forgot to take. Be sure to follow your treatment until the end.

**13. MENTION, IF NECESSARY, OF A RISK OF WITHDRAWAL SYNDROME**

If you stop taking this medicine:

It is important that you follow the treatment until the end even if you start to feel better after a few days. If you stop taking this medicine too early, your infection may not be completely cured and the symptoms of the infection may return or get worse. You could also develop resistance to this antibiotic.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist for more information.

**14. ADVICE AND HEALTH EDUCATION:**

**What to know about antibiotics?**

Antibiotics are effective in fighting infections caused by bacteria. They are not effective against virus infections.

Also, your doctor has chosen to prescribe this antibiotic because it is right for you and your current illness.

Bacteria have the ability to follow or reproduce despite the action of an antibiotic. This phenomenon is called resistance; it makes some antibiotic treatments inactive. Resistance increases through the misuse or inappropriate use of antibiotics.

You may promote the emergence of resistance bacteria and thus delay your recovery or even inactivate this drug, if you do not respect:

- The dose to take
- The moments of taking
- The duration of treatment

**Therefore, to preserve the effectiveness of this medicine:**

- 1) Only use an antibiotic when your doctor has prescribed it.
- 2) Strictly observe your prescription.
- 3) Do not reuse an antibiotic without a prescription even if you think you are fighting a seemingly similar illness.
- 4) Never give your antibiotic to another person, it may not be suitable for his illness.
- 5) Once your treatment is complete, report to your pharmacist all boxes started for proper and proper destruction of this medication.

**Conditions of regulation and delivery**

Table A (List I).  
**Special precautions for storage**

Store at temperature below 30°C.  
Keep out of the reach and sight of children.

Do not use after the expiry date stated on the carton box.  
This leaflet was last revised in April 2019.

Manufactured by:

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