

PACKAGE LEAFLET: Information for the patient

NEOCIL

Solution for infusion – 200 mg / 100 ml

Concentrate for solution for infusion – 100 mg / 10 ml

(Ciprofloxacin lactate)

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 side effects not listed in this leaflet, please tell your doctor or pharmacist.

What is in this leaflet:

1. What Neocil is and what it is used for
2. What you need to know before you take Neocil
3. How to take Neocil
4. Possible side effects
5. How to store Neocil
6. Other information

1. WHAT NEOCIL IS AND WHAT IT IS USED FOR

Neocil contains the active substance ciprofloxacin (as lactate). Ciprofloxacin 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

Neocil 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;
- anthrax inhalation exposure.

Ciprofloxacin may be used in the management of patients with low white blood cell count (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 Neocil.

Children and adolescents

Neocil 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.

Neocil 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 NEOCIL

Do not take Neocil:

- if you are allergic (hypersensitive) to the active substance, to other quinolone drugs or to any of the other ingredients of Neocil (see section 6);
- if you are taking tizanidine (see Section 2: Taking other medicines).

Take special care with Neocil

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

Before you are given Neocil

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 Neocil;
- 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 Neocil 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 Neocil);
- 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 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]).

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.

While under treatment with Neocil

Tell your doctor immediately, if any of the following occurs **during treatment with Neocil**.

Your doctor will decide whether treatment with Neocil needs to be stopped.

- **Severe, sudden allergic reaction** (an anaphylactic reaction/shock, angio-oedema). Even with the first dose, there is a rare chance that you may experience a severe allergic reaction with the following symptoms: tightness in the chest, feeling dizzy, feeling sick or faint, or experience dizziness on standing. **If this happens, tell your doctor immediately since the administration of Neocil will have to be stopped.**
- **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 Neocil therapy. At the first sign of pain or inflammation of a tendon (for example in your ankle, wrist, elbow, shoulder or knee), stop taking Neocil, 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 Neocil and contact your doctor immediately.
- You may rarely experience symptoms of nerve damage (neuropathy) such as pain, burning, tingling, numbness and/or weakness, especially in the feet and legs or hands and arms. If this happens, stop taking Neocil and inform your doctor immediately in order to prevent the development of potentially irreversible condition.
- You may experience **psychiatric reactions** after first administration of ciprofloxacin. If you suffer from **depression** or **psychosis**, your symptoms may become worse under treatment with Neocil. In rare cases, depression or psychosis can progress to thoughts of suicide, suicide attempts, or completed suicide. If this happens, contact your doctor immediately.

- **Hypoglycemia** has been reported most often in diabetic patients, predominantly in elderly population. If this happens, contact your doctor immediately.
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 on antibiotics, including Neocil, or even several weeks after you have stopped using them. If it becomes severe or persistent or you notice that your stool contains blood or mucus, stop taking Neocil, tell your doctor immediately, as this can be life-threatening. Do not take medicines that stop or slow down bowel movements.
- 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** under treatment with Neocil. Avoid exposure to strong sunlight or artificial UV light such as sunbeds.
- Tell the doctor or laboratory staff that you are taking Neocil 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.
- Neocil 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, Neocil must be stopped immediately.
- Neocil 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.
- 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.

Prolonged, disabling and potentially irreversible serious side effects

Fluoroquinolone / quinolone antibacterial medicines, including ciprofloxacin, 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 Neocil, 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.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines.

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

The following medicines are known to interact with ciprofloxacin in your body. Using Neocil together with these medicines can influence the therapeutic effect of these 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 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);
- 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 antiarrhythmics (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).

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

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

Taking Neocil with food and drinks

Food and drinks do not affect your treatment with Neocil.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, 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 preferable to avoid the use of Neocil during pregnancy.

Do not take Neocil during breastfeeding because ciprofloxacin is excreted in breast milk and can be harmful for your child.

Driving and using machines

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

Important information about some of the ingredients of Neocil 200 mg/100 ml solution for infusion and Neocil 100 mg/10 ml concentrate for solution for infusion

- Neocil 200 mg/100 ml solution for infusion contains approximately 354 mg sodium (main component of cooking/table salt) per 100 ml of solution. This is equivalent to 17.7% of the adult recommended maximum daily dietary intake for sodium.

Talk to your pharmacist or doctor if you need 110 ml or more solution on a daily basis for a prolonged period of time, especially if you have been advised to have a low salt diet.

- Neocil 100 mg/10 ml concentrate for solution for infusion contains less than 1 mmol sodium (23 mg) per 10 ml, that is to say essentially “sodium-free”.

3. HOW TO TAKE NEOCIL

Your doctor will explain to you exactly how much Neocil you will be given as well as how often and for how long. This will depend on the type of infection you have and how severe it is.

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

Treatment usually lasts between 5 and 21 days, but may be longer for severe infections.

Before infusion, Neocil 100 mg/10 ml concentrate for solution for infusion should be diluted to a concentration of 1 – 2 mg / ml with a compatible solution for infusion.

Your doctor will give you each dose by slow infusion through a vein into your bloodstream. For children, the infusion duration is 60 minutes. In adult patients, infusion time is 60 minutes for 400 mg ciprofloxacin and 30 minutes for 200 mg ciprofloxacin. Administering the infusion slowly helps prevent immediate side effects occurring.

Remember to drink plenty of fluids while you are taking this medicine.

If you stop taking Neocil

It is important that you **finish the course of treatment** even if you begin to feel better after a few days. If you stop using 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 about the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

As with other medicines, Neocil may cause side effects, although not everybody gets them.

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

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

Uncommon (may affect up to 1 in 100 people)

- Seizure (see Section 2: Take special care with Neocil).

Rare (may affect up to 1 in 1,000 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 shock) (see Section 2: Take special care with Neocil).
- Tendon rupture, particularly affecting the large tendon at the back of the ankle (Achilles tendon) (see Section 2: Take special care with Neocil).

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) (see Section 2: Take special care with Neocil).
- 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: Take special care with Neocil).

- 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, AGEP (Acute Generalised Exanthematous Pustulosis)).

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

Common (may affect up to 1 in 10 people)

- nausea, diarrhoea, vomiting;
- joint pain and joint inflammation in children;
- local reaction at the injection site, rash;
- temporary increased amounts of substances in the blood (transaminases).

Uncommon (may affect up to 1 in 100 people)

- joint pain in adults;
- fungal superinfections;
- a high concentration of eosinophils, a type of white blood cell, increased or decreased amounts of a blood clotting factor (thrombocytes);
- decreased appetite;
- hyperactivity, agitation, confusion, disorientation, hallucinations;
- headache, dizziness, sleeping problems, taste disorders, pins and needles, unusual sensitivity to stimuli of the senses;
- eyesight problems including double vision;
- loss of hearing;

- rapid heartbeat (tachycardia), expansion of the blood vessels (vasodilation), low blood pressure;
- abdominal pain, digestive problems such as stomach upset (indigestion/heartburn), wind;
- liver disorders, increased amounts of one substance in the blood (bilirubin), jaundice (cholestatic jaundice);
- itching, hives;
- poor kidney function, kidney failure;
- pain in your muscles and bones, feeling unwell (asthenia), fever, fluid retention;
- increase in blood alkaline phosphatase (a certain substance in the blood).

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

- muscle pain, inflammation of the joints, increased muscle tone and cramping;
- inflammation of the bowel (colitis) linked to antibiotic use (can be fatal in very rare cases) (see Section 2: Take special care with Neocil);
- changes to the blood count (leukopenia, leukocytosis, neutropenia, anaemia), a drop in the number of red and white blood cells and platelets (pancytopenia), which may be fatal, bone-marrow depression which may also be fatal;
- allergic reaction, allergic swelling (oedema), rapid swelling of the skin and mucous membranes (angiooedema) (see Section 2: Take special care with Neocil);
- increased blood sugar (hyperglycemia);
- decreased blood sugar (hypoglycaemia) (see Section 2: Take special care with Neocil);
- anxiety reaction, strange dreams, depression (potentially leading to thoughts of suicide, suicide attempts, or completed suicide), mental disturbances (psychotic reactions potentially leading to thoughts of suicide, suicide attempts, or completed suicide) (see Section 2: Take special care with Neocil);
- decreased skin sensitivity, tremor, migraine, disorder of sense of smell (olfactory disorders);
- tinnitus, impaired hearing;
- fainting, inflammation of the blood vessel (vasculitis);
- shortness of breath including asthmatic symptoms;
- pancreatitis;
- hepatitis, death of liver cells (liver necrosis) very rarely leading to life-threatening liver failure

(see Section 2: Take special care with Neocil);

- sensitivity to light (see Section 2: Take special care with Neocil), small, pin-point bleeding under the skin (petechiae);
- blood or crystals in urine, urinary tract inflammation;
- excessive sweating;
- increased levels of the enzyme amylase.

Very rare (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: Take special care with Neocil);
- allergic reaction called serum sickness-like reaction (see Section 2: Take special care with Neocil);
- disturbed coordination, unsteady walk (gait disturbance), pressure on the brain (intracranial pressure and pseudotumor cerebri);
- visual colour distortions;
- various skin eruptions or rashes;
- worsening of the symptoms of myasthenia gravis (see Section 2: Take special care with Neocil).

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

- feeling highly excited (mania) or feeling great optimism and overactivity (hypomania);
- 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);
- influence on blood clotting (in patients treated with vitamin K antagonists);
- 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.

Very rare cases of long lasting (up to months or years) or permanent adverse drug reactions, such as tendon inflammations, tendon rupture, joint pain, pain in the limbs, difficulty in walking, abnormal sensations such as pins and needles, tingling, tickling, burning, numbness or pain

(neuropathy), depression, fatigue, sleep disorders, memory impairment, as well as impairment of hearing, vision, and taste and smell have been associated with 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.

5. HOW TO STORE NEOCIL

Keep the medicine out of the sight and reach of children!

Do not use Neocil after the expiry date which is stated on the packaging.

Do not store above 25°C!

Do not refrigerate or freeze as crystals may form if the medicine gets too cold. If you see crystals in your medicine, do not use the medicine and tell your doctor, nurse or pharmacist immediately.

Store in the original packaging to protect it from light.

6. OTHER INFORMATION

Neocil 200 mg/100 ml solution for infusion

The active substance is ciprofloxacin lactate.

100 ml solution contain ciprofloxacin lactate equivalent to 200 mg ciprofloxacin base.

The other ingredients are: sodium chloride, lactic acid, disodium edetate, hydrochloric acid and water for injection.

Neocil 100 mg/10 ml concentrate for solution for infusion

The active substance is ciprofloxacin lactate.

Each ampoule 10 ml contains ciprofloxacin lactate equivalent to 100 mg ciprofloxacin base.

The other ingredients: lactic acid, disodium edetate, hydrochloric acid and water for injection.

Contents of the packSolution for infusion:

Box with one glass bottle of 100 ml.

Concentrate for solution for infusion:

Box with 5 ampoules of 10 ml.

Box with 100 ampoules of 10 ml (for hospital use only).

Marketing Authorisation Holder (MAH) and Manufacturer:

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