**Norfloxacin 400 mg tablets, film-coated tablets**

norfloxacin

**What is norfloxacin and what is it used for?**Norfloxacin belongs to the group of fluoroquinolones, a group of antibacterial medicines. Norfloxacin is used in the treatment of infections caused by bacteria that are sensitive to norfloxacin, such as urinary tract infections.

**When should you not use this medicine or use it with extra caution?**

**When should you not use this medicine?**

* You are allergic to any of the substances in this medicine. These substances can be found in section 6.
* You have experienced tendon problems when using this type of medicine.
* You are pregnant or think you might be pregnant (see "Fertility, pregnancy, and breastfeeding" below).
* You are breastfeeding.
* You have previously had a poor reaction to a similar medicine.
* The patient is a child or still growing.
* Do not use Norfloxacin if any of the above warnings apply to you. If you are unsure, consult your doctor or pharmacist before using Norfloxacin Sandoz.

**When should you use extra caution with this medicine?**Before using this medicine, If you have experienced a severe side effect in the past when using a quinolone or fluoroquinolone, you should not use fluoroquinolones/quinolone antibiotics, including this medicine. Inform your doctor as soon as possible if this applies to you.

**Contact your doctor if you:** experience a severe allergic reaction (anaphylactic reaction) at the beginning or during treatment with Norfloxacin (see section 4: "Uncommon serious side effects: allergic reaction"). In such cases, treatment with Norfloxacin should be discontinued immediately, and appropriate measures should be taken, such as administration of antihistamines, glucocorticosteroids, sympathomimetics, and, if necessary, ventilation.

develop tendon inflammation or tendon rupture during treatment. In rare cases, joint pain, swelling, tendon inflammation, or tendon rupture may occur. You are at greater risk if you are over 60 years old, have undergone organ transplantation, have kidney problems, or are being treated with corticosteroids. Tendon inflammation and tendon rupture can occur within the first 48 hours of treatment and even several months after discontinuing this medicine. If you experience the first signs of tendon pain or inflammation (e.g., in your ankle, wrist, elbow, shoulder, or knee), discontinue the use of this medicine. Also, immediately contact your doctor and rest the affected area. Avoid any unnecessary physical exertion as it increases the risk of tendon rupture.

experience nerve damage. In rare cases, you may experience nerve damage (neuropathy), such as pain, burning sensation, tingling, numbness, and weakness, especially in the feet, legs, hands, or arms. If this occurs, discontinue the use of this medicine immediately. Also, contact your doctor immediately to prevent possible long-term effects.

* have had seizures or a cerebral hemorrhage in the past.
* have had a disease that causes seizures, such as epilepsy.
* have impaired kidney function. Your doctor may adjust the dosage.
* have heart problems. You should use this type of medicine with caution if you were born with a prolonged QT interval or if it runs in your family (as determined by an electrocardiogram, ECG), if you have an imbalance of electrolytes in the blood (particularly low potassium or magnesium levels), if you have a very slow heart rate (bradycardia), if you have a weak heart (heart failure), if you have had a heart attack (myocardial infarction), if you are female or elderly, or if you are using other medications that cause changes in the ECG (see section 2, "Are you taking any other medicines?").
* have a condition called myasthenia gravis, which causes muscle weakness or a family member has anemia caused by a condition called glucose-6-phosphate dehydrogenase deficiency (also known as G6PD deficiency).
* experience diarrhea, especially if it is severe, prolonged, or contains blood.
* have a decrease in vision or develop another eye condition while using this medicine. Seek immediate advice from an ophthalmologist (see sections "Driving and using machines" and 4, "Possible side effects").
* have been diagnosed with an enlargement or bulging of a major blood vessel (aortic aneurysm or peripheral aneurysm of a major blood vessel).
* have had a previous episode of aortic dissection (a tear in the wall of the aorta).
* have been diagnosed with leaking heart valves (valvular regurgitation).
* have a family history of aortic aneurysm or aortic dissection, congenital heart valve disease, or other risk factors or if you have been diagnosed with an enlargement or bulge of a major blood vessel (aortic aneurysm or peripheral aneurysm of a major blood vessel);
* if you have had a previous episode of aortic dissection (a tear in the wall of the aorta);
* if you have been diagnosed with leaking heart valves (valvular regurgitation);
* if you have a family history of aortic aneurysm or aortic dissection, congenital heart valve disease, or other risk factors or related conditions (such as connective tissue disorders like Marfan syndrome or vascular Ehlers-Danlos syndrome, Turner syndrome, Sjögren's syndrome [an autoimmune disease characterized by inflammation], or vascular conditions such as Takayasu arteritis, giant cell arteritis, Behçet's disease, high blood pressure, or [additional information missing]).
* known atherosclerosis, rheumatoid arthritis [a joint condition], or endocarditis [an infection of the heart]).

have diabetes because you are at risk of hypoglycemia (low blood sugar).

**Medication:** Antibiotics from the quinolone family can cause an increase in your blood sugar levels above normal levels (hyperglycemia) or a decrease in your blood sugar levels below normal, which may lead to loss of consciousness (hypoglycemic coma) in severe cases (see section 4). This is important for people with diabetes. If you have diabetes, your blood sugar levels should be carefully monitored.

**When taking this medicine:** Go immediately to an emergency department if you experience sudden, severe pain in your abdomen, chest, or back. These may be symptoms of aortic aneurysm and aortic dissection. The risk may be increased if you are being treated with systemic corticosteroids.

Contact a doctor immediately if you experience shortness of breath, especially when lying flat in bed, or if you notice swelling in your ankles, feet, or abdomen, or if you have newly developed palpitations (a feeling of rapid or irregular heartbeat).

Long-lasting, disabling, and potentially permanent serious side effects

Fluoroquinolone/quinolone antibiotics, including this medicine, have been associated with very rare but serious side effects, some of which can last for months or years, lead to disability, or be potentially permanent. These include tendon, muscle, and joint pain in the arms and legs, problems with walking, unusual sensations such as a "tingling" or "numb" feeling, tingling, a crawling sensation, numbness or burning sensation (paresthesia), sensory disorders such as decreased vision, taste, smell, and hearing, depression, memory loss, severe fatigue, and severe sleep disorders.

If you experience any of these side effects after using this medicine, contact your doctor immediately before continuing with the treatment. You and your doctor will then decide together whether you can continue using this medicine, considering the possible use of an antibiotic from a different class.

Exposure to sunlight or ultraviolet light should be avoided during the use of Norfloxacin Sandoz, as you may develop photosensitivity.

During treatment, you should drink enough fluids to prevent norfloxacin from precipitating in the urine.

If you are unsure if these warnings apply to you, consult your doctor or pharmacist before using Norfloxacin Sandoz.

**Are you taking any other medications?**Are you taking any other medications in addition to Norfloxacin Sandoz, have you taken any recently, or are you planning to take any in the near future? Inform your doctor or pharmacist about this. This also applies to medications that can be obtained without a prescription and herbal remedies. Norfloxacin may affect the efficacy of other medications. Additionally, other medications may affect the efficacy of Norfloxacin Sandoz.

**Some medications may reduce the amount of norfloxacin that reaches the body.**Norfloxacin should be taken at least 2 hours before or 4 hours after taking the following medications: gastric acid-reducing medications (antacids) used for digestive disorders or heartburn (this does not apply to H2-receptor antagonist antacids); sucralfate used for stomach ulcers or gastritis (stomach inflammation); preparations containing calcium, magnesium, aluminum, iron, or zinc, including multivitamin preparations and minerals. If you are unsure whether the above warnings apply to you, please consult your doctor or pharmacist before using Norfloxacin Sandoz.

It is also particularly important to inform your doctor or pharmacist if you are taking any of the following medications:

* medications that can alter heart rhythm
* antiarrhythmic medications (such as quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, dofetilide, ibutilide)
* tricyclic antidepressants
* certain antibiotics (from the macrolide group)
* certain antipsychotics
* theophylline (for respiratory problems)
* anticoagulant medications, such as warfarin, phenprocoumon, or acenocoumarol
* fenbufen (for joint pain)
* didanosine (for HIV or AIDS)
* cyclosporine or mycophenolic acid (after transplants and for certain other conditions)
* probenecid (for gout)
* nitrofurantoin (for urinary tract infections, such as bladder infection)
* caffeine.

If you are unsure whether the above warnings apply to you, please consult your doctor or pharmacist before using Norfloxacin Sandoz.

**What to be aware of regarding food and drink?**Take Norfloxacin with a glass of water. Take it at least 1 hour before or 2 hours after food or milk.

**Pregnancy, breastfeeding, and fertility**If you are pregnant, think you might be pregnant, planning to become pregnant, or breastfeeding, please contact your doctor or pharmacist before using this medication.

Do not use Norfloxacin if you are pregnant or planning to become pregnant, as it may have harmful effects on the baby.

If you are using Norfloxacin Sandoz, do not breastfeed, as small amounts of the medication may pass into breast milk.

**Driving and using machinery**Norfloxacin may affect your reaction time. Therefore, do not drive a car or operate machinery, especially if you experience dizziness, headache, fatigue, or nausea. These effects are more likely to occur at the beginning of treatment, with dose increases or changes in medication, and with concurrent alcohol use.

You may experience sudden temporary loss of vision or possible fainting for a short time. If you experience these symptoms, do not drive or operate machinery. Make sure you know how you react to this medication before driving or operating machinery. Consult your doctor if you are unsure.

Norfloxacin contains sodium.

This medication contains less than 1 mmol of sodium (23 mg) per tablet, which means it is essentially "sodium-free."

**How to use this medication?**Always take this medication exactly as your doctor has instructed you. If you are unsure about the correct usage, please contact your doctor or pharmacist. During treatment, it is important to drink an adequate amount of fluids to prevent norfloxacin from precipitating in the urine.

**Method of administration:** Take the tablets at least 1 hour before or 2 hours after a meal, dairy products, or multivitamins.

Swallow the tablets whole with a full glass of water. Take the tablets in the morning and evening. If taking one tablet per day, always take it at the same time of day.

**Dosage**

**The usual dosage is:**

* For less severe infections: 1 tablet twice daily for 3 days.
* For more severe infections: 1 tablet twice daily for 7-10 days.
* For very severe infections: 1 tablet twice daily for 2-3 weeks.
* The dosage depends on your condition and its severity.
* Users with kidney disease: Dosage adjustment may be necessary.
* Elderly: No dosage adjustment is necessary.
* Children: The use of this medication is not recommended for children and adolescents who are still growing.

**Have you taken too much of this medication?**If you have taken too much Norfloxacin Sandoz, immediately contact your doctor or pharmacist.

**Have you forgotten to take this medication?**If you have forgotten to take a tablet, skip the missed dose and take the next dose at the usual time.

Never take a double dose to make up for the missed dose.

**If you stop taking this medication**Always complete the prescribed course of treatment, even if you start feeling better after a few days.
If you have any other questions about the use of this medication, please contact your doctor or pharmacist.

**Possible Side Effects**Like any medication, this medication can cause side effects. Not everyone experiences them.

**Serious side effects**If any of the following side effects occur, stop using this medication and immediately seek medical attention from your doctor or the emergency department of the nearest hospital:

**Common serious side effects (occur in less than 1 in 100 people):** Allergic reaction - signs may include swelling of the face, lips, tongue, or throat (which may make breathing or swallowing difficult). Severe hypersensitivity reaction with (high) fever, red skin rash, joint pain, and/or eye inflammation (Stevens-Johnson syndrome). Seizures/convulsions. Severe abdominal and back pain (a sign of inflamed pancreas).

**Rare serious side effects (occur in less than 1 in 1,000 people):** Intestinal inflammation called colitis (or antibiotic-associated colitis), which causes prolonged severe watery diarrhea with abdominal cramps and fever.

**Very rare serious side effects (occur in less than 1 in 10,000 people):** Yellowing of the skin and eyes, unusual fatigue or fever, dark urine (signs of inflammation and damage to the liver).

**Common (occur in less than 1 in 10 people):** Blood disorder (deficiency of white blood cells) associated with increased susceptibility to infections (leukopenia, neutropenia). Increase in certain white blood cells. Changes in liver function test results. Headache, dizziness, lightheadedness, drowsiness. Nausea, abdominal pain and cramps, digestive disorders, or diarrhea. Skin rash.

**Uncommon (occur in less than 1 in 100 people):** Blood disorder (deficiency of blood platelets) accompanied by bruising and tendency to bleed (thrombocytopenia). Anemia resulting from excessive breakdown of blood (hemolytic anemia). Paleness and fatigue. This can be caused by anemia, especially in patients with a deficiency of "glucose-6-phosphate dehydrogenase" due to loss of red blood cells. Fatigue, insomnia, poor sleep. Mood changes, severe depression, a feeling of nervousness (anxiety), irritability, disorientation, confusion, severe mental illness with loss of contact with reality (psychosis), perceptions of things that are not there (hallucinations). Tingling in hands and feet. Neurological disorder (Guillain-Barré syndrome). This condition weakens you and can cause breathing problems. Worsening of a specific disease called myasthenia gravis (this disease causes muscle weakness). Tinnitus (ringing in the ears). Changes in vision, excessive tearing. Heart palpitations. Loss of appetite, excessive production of stomach acid, diarrhea, and vomiting. Abnormal results in liver function tests. Increased or decreased urine production, drowsiness, confusion, nausea. Crystals in the urine (crystalluria), abnormal results in kidney function tests. Red or purple pinpoint spots under the skin; red blisters and bumps; skin inflammation (dermatitis), skin reactions to sunlight. Rash with itching and formation of hives (urticaria). Vaginal fungal infection. Muscle and joint pain and swelling. Tendon pain and swelling, often in the ankles. This is more common in older people or those using steroids such as prednisolone, dexamethasone, or hydrocortisone. Try to rest the affected areas until you consult a doctor.

**Rare (occur in less than 1 in 1,000 people):** Rupture of the Achilles tendon.

**Very rare (occur in less than 1 in 10,000 people):** Muscle contractions, fever, reddish-brown urine.

Very rare cases of prolonged (lasting months or years) or permanent side effects, such as tendon inflammation, tendon rupture, joint pain, pain in arms or legs, difficulty walking, unusual sensations like a "tingling" feeling, tingling, itching, burning or numbness, or pain (neuropathy), depression, fatigue, sleep disorders, memory loss, and also reduction in hearing, vision, taste, and smell, have been associated with the use of quinolone and fluoroquinolone antibiotics. In some cases, independent of pre-existing risk factors.

In patients receiving fluoroquinolones, cases have been reported of enlargement and weakening of the wall of the aorta or a tear in the inner wall of the aorta (aneurysms and dissections). This can lead to aortic rupture, which can be fatal. Cases of leaking heart valves have also been reported. See also section 2.

**How to store this medicine?**

Keep out of sight and reach of children.

Do not use this medicine after the expiry date stated on the box and blister. The expiry date is followed by "Exp.:". It includes a month and a year. The last day of that month is the expiry date.