

PACKAGE LEAFLET: INFORMATION FOR THE USER

NOLICIN

400 mg film• coated tablets

NORFLOXACIN

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

1. What Nolicin is and what it is used for
2. Before you take Nolicin
3. How to take Nolicin
4. Possible side effects
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6. Further information

1. WHAT NOLICIN IS AND WHAT IT IS USED FOR

Nolicin is an antimicrobial medicine from the group of quinolones. ATC code: J01MA06.

It works by destroying the bacteria that are sensitive to it and cause infection in the human body.

It is intended for the treatment of:

- infection of the urinary organs and prostate,
- infectious diarrhoea,
- gonorrhoea.

It is also used for prevention of:

- infection of urinary organs,
- diarrhea while traveling,
- infections in patients with weakened resistance.

2. BEFORE YOU TAKE NOLICIN

Do not take Nolicin:

- If you are allergic (hypersensitive) to norfloxacin, or other medicine from the group of quinolones or to the other ingredients of Nolicin,
- If you are pregnant or breast• feeding.

Nolicin should not be used in children and adolescents during the period of growth.

Be careful with the Nolicin

Tell your doctor if you have epilepsy or other disorders of the central nervous system (especially the disturbances that can boost muscle spasms). In such cases, the side effects can occur more often.

During treatment with Nolicin you can become hypersensitive to sun's rays and artificial ultraviolet light. Therefore, we recommend no subjection to excessive sunlight or artificial ultraviolet light.

If you have reduced function of your kidneys, a doctor will prescribe the appropriate lower dose. We recommend that during treatment with Nolicin you drink enough fluids. Consult a doctor about how much fluid per day is most appropriate for you.

If during the treatment with Nolicin you experience aches of tendons, consult a doctor. Avoid physical activity.

Caution is necessary in taking medicines of this type if you have had a prolonged QT• interval already at birth or have it in a family history (it is evident from the electrocardiogram, or the records the electrical activity of the heart), if you have an imbalance of salts in the blood (especially small concentration of potassium or magnesium), if you have a very slow heart rate (bradycardia), if you have a weakened heart, if you have already had a heart attack (myocardial infarction). If you are a woman or an elderly person, or if you are taking other medicines that cause changes in the electrocardiogram (see chapter taking other medicines).

Taking other medicines with Nolicin

Tell your doctor or pharmacist if you are taking other medicines, if you have recently used or you may use other medicines, including medicines that can be obtained without a prescription.

If you are taking medicines for heartburn – antacids, sucralfate, medicines containing iron, aluminum, bismuth, calcium, magnesium or zinc, reduces the absorption of norfloxacin we recommend that you take a medicine Nolicin two hours before these medicines.

If during the treatment with Nolicin you are taking medicine for the treatment of chronic bronchitis and asthma (theophylline) or medicines for braking of the immune system (Cyclosporine), you may experience side effects because it can increase the amount of theophylline or Cyclosporine in the blood. A doctor will measure the quantity of the above mentioned medicines in the blood and may prescribe a lower dose.

If at the same time with Nolicin you are taking blood thinners (warfarin), it can enhance their action and bleeding.

With simultaneous treatment of corticosteroids and Nolicin there is a greater possibility for inflammation or rupture of a tendon.

Nolicin may increase the effect of some medicines to treat diabetes (sulfonylureas).

Don't take Nolicin along with medicines to treat bacterial infections of the urinary organs (nitrofurantoin) because the effect of co• administration of both medicines decreases.

You must tell the doctor if you are taking other medicines that may change your heart rhythm, medicines that belong to the group of emergency(e.g., quinidine, hydroquinidine, disopyramid, sotalol, amiodarone, dofetilid, ibutilid), tricyclic antidepressants, some antimicrobial medicines (which belong to the group of macrolide), some antipsychotics.

Taking food and drinks with Nolicin

Nolicin can be taken on empty stomach or during the meal. Do not take it with milk or yoghurt, because liquid dairy products reduce the amount of norfloxacin that reaches into the blood. You should take Nolicin one hour before a milk meal or two hours after. You should not drink alcohol.

Pregnancy and breastfeeding

Consult a doctor or pharmacist before taking any medicine.

The risk of side effects on the fetus cannot be excluded. If you are pregnant, a doctor may prescribe Nolicin only when the benefit to you is greater than the danger for the child.

Do not breast• feed while taking the medicine Nolicin.

The management of vehicles and machines

Trigonic, a medicine with the possible influence of the psychophysical abilities (a warning when driving motor vehicles and using machines).

Since the medicine Nolicin may reduce the ability of the reactions, be careful with driving and using machines, until you know how your body reacts to the medicine. If you are simultaneously drinking alcoholic beverages, undesirable effects can increase.

Additional information

Azo dye E110 may cause allergic reactions.

3. HOW TO TAKE NOLICIN

When taking the medicine Nolicin exactly follow the doctor's instructions. If you are in doubt, consult a doctor or pharmacist.

The doctor will adjust a dose and duration of treatment according to your illness. Always take tablet with a glass of water or tea.

The usual dose is 1 tablet (400 mg) 2 times a day. Treatment of infection of urinary organs or digestive organs lasts 3- 14 days, and chronic bacterial prostatitis lasts more weeks.

To prevent infection of urinary organs take half a tablet of Nolicin (200 mg) per day, and for the prevention of traveling diarrhea take 1 tablet (400 mg) per day. If you have a weakened resistance, take 1 tablet (400 mg) 2 times a day. If you have impaired kidney function, your doctor will adjust the dose.

If you take more than you should

Too high doses can cause nausea, vomiting, diarrhea, and in severe cases dizziness, fatigue, distractions and cramps.

If you forget to take Nolicin

Do not take a double dose if you forget to take the previous dose.

If you forget to take a tablet, take it as soon as you remember, unless the time for your next dose is approaching.

If you stop taking Nolicin

Take your medicine as long as prescribed by your doctor. Even though you feel better, the infection might still be present and may return if you stop treatment too early.

If you have any further questions on the use of Nolicin ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, it may cause side effects.

Side effects are listed according to the following categories of frequency:

Very common	Appear in more than 1 in 10 patients
Common	Appear at 1 to 10 patients on 100 patients
Uncommon	Appear at 1 to 10 patients on 1000 patients
Rare	Appear at 1 to 10 patients on 10000 patients
Very rare	Appear at fewer than 1 patient in the 10000 patients
Unknown frequency	Not possible to evaluate from available data

Common

- nausea

Uncommon

- headache, drowsiness, depression, diarrhea, loss of appetite or increased number of eosinophils (Eosinophilia), decreased white blood cell count (leucopenia) or increased activity of some enzymes (transaminase, alkaline phosphatase and lactate dehydrogenase)

Diarrhea is just extremely persistent. Whereas, as such it may be a sign of a special form of inflammation of the colon (of pseudo membranous colitis), in such a case, consult with a doctor.

Rare:

- fatigue, elevated levels of creatinine in the blood or urine, and reduced the proportion of red blood cells (hematocrit) in the blood

Very rare:

- drowsiness, distractions, restlessness, irritability, fear, delusions or auditory hallucinations and noise in the ears, hypersensitivity reactions, such as itching, rash, urticaria, or heavier forms of hypersensitivity reactions such as anaphylactic shock, severe skin reactions, inflammation, or rupture of a tendon (usually it is and other factors)

Frequency not known:

- an abnormally fast heart rhythm, mortally dangerous irregular heart rhythm, changes in heart rhythm (called "QT prolongation" and is visible from the electrocardiogram abnormalities)

If you notice any side effects, talk to your doctor or pharmacist.

5. HOW TO STORE NOLICIN

Keep out of reach and sight of children.

There are no special storage conditions.

Nolicin must not be used after the expiry date stated on the carton. The shelf life of the medicinal product is 5 years from the date of manufacture. The expiry date refers to the last day of that month.

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 Nolicin contains

- active substance is norfloxacin. Each film-coated tablet contains 400 mg of norfloxacin.
- the other substances are povidone, sodium carboxymethyl starch (typeA), microcrystalline cellulose, anhydrous colloidal silicon dioxide, magnesium stearate, and purified water in the Tablet core, and hypromellose, talc, titanium dioxide (E171), Orange dye FCF (E110), and propylene glycol (E1520) in the film
- coating.

How Nolicin looks like and contents of the Pack

Film-coated tablets are orange, round, slightly protruding, with division line on one side.

The tablet can be broken into equal halves.

There are boxes with 20 film- coated tablets in blisters. In the box there are 2 blisters of 10 tablets.

Regime of dispensing

The medicine is issued on doctor's prescription

Manufacturer

Krka, tovarna zdravil, d.d.

Šmarješka cesta 6, Novo Mesto, Slovenia

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