

**Patient Information**  
**NOROXIN<sup>®</sup>**  
**(norfloxacin)**

**400 mg Tablets**

This section contains important information about NOROXIN\* (norfloxacin), and should be read completely before you begin treatment. This section does not take the place of discussions with your doctor or health care professional about your medical condition or your treatment. This section does not list all benefits and risks of NOROXIN. The medicine described here can be prescribed only by a licensed health care professional. If you have any questions about NOROXIN, talk with your health care professional. Only your health care professional can determine if NOROXIN is right for you.

**What is NOROXIN?**

NOROXIN is an antimicrobial used to treat urinary tract infections, kidney infections, prostatitis and some forms of sexually transmitted diseases (specifically gonorrhea), caused by certain germs called bacteria. NOROXIN kills many of the types of bacteria that can infect the bladder, kidneys, prostate gland and urethra and has been shown in clinical trials to be safe and effective for the treatment of these bacterial infections. NOROXIN is not effective in the treatment of syphilis.

You should contact your doctor if you think your condition is not improving while taking NOROXIN.

NOROXIN Tablets contain 400 mg of active drug.

**How and when should I take NOROXIN?**

NOROXIN is usually taken twice a day for 3 to 28 days depending on the condition for which you are being treated. For gonorrhea it is given as a single dose of 2 pills taken at one time. It should be swallowed whole and taken with a large glass of water at least 1 hour before or 2 hours after a meal. Try to take the tablet at the same time each day.

You may begin to feel better quickly; however, in order to make sure that all bacteria are killed, you should complete the full course of medication. Do not take more than the prescribed dose of NOROXIN even if you missed a dose by mistake. You should not take a double dose.

**Who should not take NOROXIN?**

You should not take NOROXIN if you have ever had a severe allergic reaction to any of the group of antimicrobials known as "quinolones" such as ciprofloxacin or levofloxacin. If you develop hives, difficulty breathing, or other symptoms of a severe allergic reaction, seek emergency treatment right away. If you develop a skin rash, you should stop taking NOROXIN and call your health care professional.

You should avoid NOROXIN if you have a rare condition known as congenital prolongation of the QTc interval. If you or any of your family members have this condition you should inform your health care professional. You should avoid NOROXIN if you are being treated for heart rhythm disturbances with certain medicines such as quinidine, procainamide, amiodarone or sotalol. Inform your health care professional if you are taking a heart rhythm drug or if you have any problems with your heart rhythm.

You should also avoid NOROXIN if the amount of potassium in your blood is low. Low potassium can

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sometimes be caused by medicines called diuretics such as furosemide and hydrochlorothiazide. If you are taking a diuretic medicine you should speak with your health care professional.

If you are pregnant or planning to become pregnant while taking NOROXIN, talk to your doctor before taking this medication. NOROXIN is not recommended for use during pregnancy or nursing, as the effects on the unborn child or nursing infant are unknown.

NOROXIN is not recommended for children.

### **What are the possible side effects of NOROXIN?**

NOROXIN is generally well tolerated. The most common side effects caused by NOROXIN, which are usually mild, include dizziness, nausea, heartburn, headache, and rash. If a rash occurs stop taking NOROXIN and call your health care provider. Less common side effects may include changes in hearing and pain, burning, tingling, numbness, and/or weakness in arms or legs.

If you should develop hives, trouble breathing, wheezing, or other signs of an allergic reaction seek help immediately.

You should be careful about driving or operating machinery until you are sure NOROXIN is not causing dizziness.

Pain, swelling, and tears of the Achilles, shoulder, or hand tendons have been reported in patients receiving fluoroquinolones, including NOROXIN. The risk for tendon effects is higher if you are over 65 years of age, or if you are taking corticosteroids. If you develop pain, swelling, or tear of a tendon you should stop taking NOROXIN, avoid exercise and strenuous use of the affected area, and contact your health care provider.

Convulsions have been reported in patients receiving quinolone antibiotics. Be sure to let your physician know if you have a history of convulsions. Quinolones, including NOROXIN, have been rarely associated with other central nervous system events including confusion, tremors, hallucinations, anxiety, and depression.

Quinolones, including NOROXIN, may worsen the signs of myasthenia gravis leading to difficulty breathing which may be life-threatening. If you develop this symptom contact your health care provider right away.

NOROXIN may cause a rare heart problem known as prolongation of the QTc interval. This condition can cause an abnormal heartbeat and can be very dangerous. The chances of this event are increased in those with a family history of prolonged QTc interval, low potassium (hypokalemia), and those who are taking drugs to control heart rhythm called class IA (quinidine, procainamide), or class III (amiodarone, sotalol) antiarrhythmic agents. You should call your healthcare provider right away if you have symptoms of prolongation of the QTc interval including prolonged heart palpitation (a change in the way your heart beats) or a loss of consciousness (fainting spells).

Diarrhea that usually ends after treatment is a common problem caused by antimicrobials. A more serious form of diarrhea can occur during or up to 2 months after the use of antibiotics. This has been reported with all antimicrobials, including NOROXIN. If you develop a watery or bloody stool, with or without stomach cramps and fever, contact your physician as soon as possible.

Sun sensitivity (photosensitivity), which can appear as skin eruption or severe sunburn, can occur in some patients taking quinolone antimicrobials after exposure to sunlight or artificial ultraviolet light (UV) (e.g., tanning beds). NOROXIN has been infrequently associated with photosensitivity. Avoid excessive exposure to sunlight or artificial UV light while taking NOROXIN. Use a sunscreen and wear protective clothing if you are exposed to the sun. If photosensitivity develops, contact your physician.

NOROXIN can cause crystals to form in the urine of patients taking it if they are dehydrated. Make sure you drink plenty of water while taking NOROXIN.

If you notice any side effects not mentioned in this section or you have any concerns about the side effects you are experiencing, please inform your health care professional.

### **What about other medicines I am taking?**

Tell your doctor about all other prescription and non-prescription medicines, dietary supplements and herbals you are taking. You should avoid taking NOROXIN with certain medicines used to treat an abnormal heartbeat. These include quinidine, procainamide, amiodarone, and sotalol.

Some medicines also produce an effect on the electrocardiogram test, including cisapride, erythromycin, some antidepressants, and some antipsychotic drugs. These may increase the risk of heart beat problems when taken with NOROXIN.

Many antacids and multivitamins may interfere with the absorption of NOROXIN and may prevent it from working properly. You should take NOROXIN either 2 hours before or 2 hours after taking these products.

### **Remember**

- Take your dose of NOROXIN every day.
- Complete the course of medication even if you are feeling better.
- Keep this medication out of the reach of children.
- This information does not take the place of discussions with your doctor or health care professional about your medical condition or your treatment.
- For more complete information about NOROXIN request full prescribing information from your health care professional, pharmacist, or visit our website at [www.merck.com](http://www.merck.com).

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