MEDICATION GUIDE

NOROXIN® [nor-AHK-sin]
(norfloxacin)
Tablets

Read the Medication Guide that comes with NOROXIN* before you start taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or your treatment.

What is the most important information I should know about NOROXIN?

NOROXIN belongs to a class of antibiotics called fluoroquinolones. NOROXIN can cause side effects that may be serious or even cause death. If you develop any of the following serious side effects, get medical help right away. Talk with your healthcare provider about whether you should continue to take NOROXIN.

1. **Tendon rupture or swelling of the tendon (tendinitis)**
   - **Tendon problems can happen in people of all ages who take NOROXIN.** Tendons are tough cords of tissue that connect muscle to bones. Symptoms of tendon problems may include:
     - Pain, swelling, tears and inflammation of tendons including the back of the ankle (Achilles), shoulder, hand, or other tendon sites.

   - **The risk of getting tendon problems while you take NOROXIN is higher if you:**
     - are over 60 years of age
     - are taking steroids (corticosteroids)
     - have had a kidney, heart or lung transplant

   - **Tendon problems can happen in people who do not have the above risk factors when they take NOROXIN. Other reasons that can increase your risk of tendon problems can include:**
     - physical activity or exercise
     - kidney failure
     - tendon problems in the past, such as in people with rheumatoid arthritis (RA)

   - **Call your healthcare provider right away at the first sign of tendon pain, swelling or inflammation.** Stop taking NOROXIN until tendinitis or tendon rupture has been ruled out by your healthcare provider. Avoid exercise and using the affected area. The most common area of pain and swelling is the Achilles tendon at the back of your ankle. This can also happen with other tendons.

   - **Talk to your healthcare provider about the risk of tendon rupture with continued use of NOROXIN.** You may need a different antibiotic that is not a fluoroquinolone to treat your infection.

   - **Tendon rupture can happen while you are taking or after you have finished taking NOROXIN.** Tendon ruptures have happened up to several months after patients have finished taking their fluoroquinolone.

   - **Get medical help right away if you get any of the following signs or symptoms of a tendon rupture:**

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- hear or feel a snap or pop in a tendon area
- bruising right after an incident in a tendon area
- unable to move the affected area or bear weight

2. **Worsening of myasthenia gravis (a disease which causes muscle weakness)**
   Fluoroquinolones like NOROXIN may cause worsening of myasthenia gravis symptoms, including muscle weakness and breathing problems. Call your healthcare provider right away if you have any worsening muscle weakness or breathing problems.

See the section "What are the possible side effects of NOROXIN?" for more information about side effects.

What is NOROXIN?

NOROXIN is a fluoroquinolone antibiotic medicine used in adults to treat certain infections caused by certain germs called bacteria. It is not known if NOROXIN is safe and works in children under 18 years of age. Children have a higher chance of getting bone and joint (musculoskeletal) problems while taking NOROXIN.

Sometimes infections are caused by viruses rather than by bacteria. Examples include viral infections in the sinuses and lungs, such as the common cold or flu. Antibiotics including NOROXIN do not kill viruses.

Call your healthcare provider if you think your condition is not getting better while you are taking NOROXIN.

Who should not take NOROXIN?

Do not take NOROXIN if you:

- have ever had a severe allergic reaction to an antibiotic known as a fluoroquinolone, or are allergic to any of the ingredients in NOROXIN. Ask your healthcare provider if you are not sure. See the list of ingredients in NOROXIN at the end of this Medication Guide.
- have had tendinitis or tendon rupture with the use of NOROXIN or another fluoroquinolone antibiotic.

What should I tell my healthcare provider before taking NOROXIN?

See "**What is the most important information I should know about NOROXIN?**"

Tell your healthcare provider about all your medical conditions, including if you:

- have tendon problems
- have a disease that causes muscle weakness (myasthenia gravis)
- have central nervous system problems (such as epilepsy)
- have nerve problems
- have or anyone in your family has an irregular heartbeat, especially a condition called "QTc prolongation"
- have low potassium (hypokalemia)
- have a slow heartbeat called bradycardia
- have a history of seizures
- have kidney problems. You may need a lower dose of NOROXIN if your kidneys do not work well.
- have rheumatoid arthritis (RA) or other history of joint problems
- are pregnant or planning to become pregnant. It is not known if NOROXIN will harm your unborn child.

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- are breast-feeding or planning to breast-feed. It is not known if NOROXIN passes into breast milk. You and your healthcare provider should decide whether you will take NOROXIN or breast-feed.

Tell your healthcare provider about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal and dietary supplements. NOROXIN and other medicines† can affect each other causing side effects. Especially tell your healthcare provider if you take:

- an NSAID (Non-Steroidal Anti-Inflammatory Drug). Many common medicines for pain relief are NSAIDs. Taking an NSAID while you take NOROXIN or other fluoroquinolones may increase your risk of central nervous system effects and seizures. See "**What are the possible side effects of NOROXIN?**"
- glyburide (Micronase, Glynase, Diabeta, Glucovance). See "**What are the possible side effects of NOROXIN?**"
- a blood thinner (warfarin, Coumadin, Jantoven)
- a medicine to control your heart rate or rhythm (antiarrhythmics). See "**What are the possible side effects of NOROXIN?**"
- an anti-psychotic medicine
- a tricyclic antidepressant
- erythromycin
- a water pill (diuretic)
- a steroid medicine. Corticosteroids taken by mouth or by injection may increase the chance of tendon injury.
- probenecid (Probalan, Col-probenecid)
- cyclosporine (Gengraf, Sandimmune, Neoral)
- products that contain caffeine
- clozapine (Fazaclo ODT, Clozaril)
- ropinirole (Requip, Requip XL)
- tacrine (Cognex)
- tizanidine (Zanaflex)
- theophylline (Theo-24, Elixophyllin, Theochron, Uniphyl, Theolair)
- cisapride (Propulsid)
- certain medicines may keep NOROXIN from working correctly. Take NOROXIN either 2 hours before or 2 hours after taking these products:
  - an antacid, multivitamin or other product that has iron or zinc
  - sucralfate (Carafate)
  - didanosine (Videx, Videx EC)

- You should not take the medicine nitrofuantoin (furadantin, macrodantin, macrobid) while taking NOROXIN.

Ask your healthcare provider if you are not sure if your medicine is listed above.

Know the medicines you take. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine.

How should I take NOROXIN?

- Take NOROXIN exactly as prescribed by your healthcare provider.
- NOROXIN is usually taken every 12 hours for patients with normal kidney function.
- Take NOROXIN with a glass of water.
- Drink plenty of fluids while taking NOROXIN.

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- Take NOROXIN at least one hour before or 2 hours after a meal or having milk or other dairy products.
- Do not skip any doses, or stop taking NOROXIN even if you begin to feel better, until you finish your prescribed treatment, unless:
  - you have tendon effects (see "**What is the most important information I should know about NOROXIN?**"),
  - you have a serious allergic reaction (see "**What are the possible side effects of NOROXIN?**"), or
  - your healthcare provider tells you to stop. This will help make sure that all of the bacteria are killed and lower the chance that the bacteria will become resistant to NOROXIN. If this happens, NOROXIN and other antibiotic medicines may not work in the future.
- If you miss a dose of NOROXIN, take it as soon as you remember. Do not take two doses of NOROXIN at the same time. Do not take more than 2 doses of NOROXIN in one day.
- If you take too much, call your healthcare provider or get medical help immediately.

What should I avoid while taking NOROXIN?

- NOROXIN can make you feel dizzy and lightheaded. Do not drive, operate machinery, or do other activities that require mental alertness or coordination until you know how NOROXIN affects you.
- Avoid sunlamps and tanning beds, and try to limit your time in the sun. NOROXIN can make your skin sensitive to the sun (photosensitivity) and the light from sunlamps and tanning beds. You could get severe sunburn, blisters or swelling of your skin. If you get any of these symptoms while taking NOROXIN, call your healthcare provider right away. You should use sunscreen and wear a hat and clothes that cover your skin if you have to be in sunlight.

What are the possible side effects of NOROXIN?

NOROXIN can cause side effects that may be serious or even cause death. See "**What is the most important information I should know about NOROXIN?**"

Other serious side effects of NOROXIN include:

- **Central Nervous System Effects.** Seizures have been reported in people who take fluoroquinolone antibiotics including NOROXIN. Tell your healthcare provider if you have a history of seizures. Ask your healthcare provider whether taking NOROXIN will change your risk of having a seizure.

  Central Nervous System (CNS) side effects may happen as soon as after taking the first dose of NOROXIN. Talk to your healthcare provider right away if you get any of these side effects, or other changes in mood or behavior:
  - feel lightheaded
  - seizures
  - hear voices, see things, or sense things that are not there (hallucinations)
  - feel restless
  - tremors
  - feel anxious or nervous
  - confusion
  - feel more suspicious (paranoia)

- **Serious allergic reactions.** Allergic reactions can happen in people who take fluoroquinolones, including NOROXIN, even after only one dose. Stop taking NOROXIN and get emergency medical help right away if you get any of the following symptoms of a severe allergic reaction:
  - hives
  - trouble breathing or swallowing

- swelling of the lips, tongue, face
- throat tightness, hoarseness
- rapid heartbeat
- faint
- yellowing of the skin or eyes. Stop taking NOROXIN and tell your healthcare provider right away if you get yellowing of your skin or white part of your eyes, or if you have dark urine. These can be signs of a serious reaction to NOROXIN (a liver problem).

- **Skin rash.** Skin rash may happen in people taking NOROXIN, even after only one dose. Stop taking NOROXIN at the first sign of a skin rash and call your healthcare provider. Skin rash may be sign of a more serious reaction to NOROXIN.

- **Serious heart rhythm changes (QTc prolongation and torsade de pointes).** Tell your healthcare provider right away if you have a change in your heart beat (a fast or irregular heartbeat), or if you faint. 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 happening are higher in people:
  - who are elderly
  - with a family history of prolonged QTc interval
  - with low blood potassium (hypokalemia)
  - who take certain medicines to control heart rhythm (antiarrhythmics)

- **Intestine infection (Pseudomembranous colitis).** Pseudomembranous colitis can happen with most antibiotics, including NOROXIN. Call your healthcare provider right away if you get watery diarrhea, diarrhea that does not go away, or bloody stools. You may have stomach cramps and a fever. Pseudomembranous colitis can happen 2 or more months after you have finished your antibiotic.

- **Changes in sensation and possible nerve damage (Peripheral Neuropathy).** Damage to the nerves in arms, hands, legs, or feet can happen in people taking fluoroquinolones, including NOROXIN. Talk with your healthcare provider right away if you get any of the following symptoms of peripheral neuropathy in your arms, hands, legs, or feet:
  - pain
  - burning
  - tingling
  - numbness
  - weakness

  NOROXIN may need to be stopped to prevent permanent nerve damage.

- **Low blood sugar (hypoglycemia).** People taking NOROXIN and other fluoroquinolone medicines with the oral anti-diabetes medicine glyburide (Micronase, Glynase, Diabeta, Glucovance) can get low blood sugar (hypoglycemia) which can sometimes be severe. Tell your healthcare provider if you get low blood sugar while taking NOROXIN. Your antibiotic medicine may need to be changed.

- **Sensitivity to sunlight (photosensitivity).** See "**What should I avoid while taking NOROXIN?**"

The most common side effects of NOROXIN include:
- dizziness
- nausea
- diarrhea
- heartburn
- headache
- stomach (abdominal) cramping

- weakness
- changes in certain liver function tests

These are not all the possible side effects of NOROXIN. Tell your healthcare provider about any side effect that bothers you or that does not go away.

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store NOROXIN?

Store between 59-86°F (15-30°C).
Keep container closed tightly.

Keep NOROXIN and all medicines out of the reach of children.

General Information about NOROXIN

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use NOROXIN for a condition for which it is not prescribed. Do not give NOROXIN to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about NOROXIN. If you would like more information about NOROXIN, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about NOROXIN that is written for healthcare professionals. For more information call 1-800-622-4477.

What are the ingredients in NOROXIN?

Active ingredient: norfloxacin

Inactive ingredients: cellulose, croscarmellose sodium, hydroxypropyl cellulose, hydroxypropyl methylcellulose, magnesium stearate and titanium dioxide

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This Medication Guide has been approved by the U.S. Food and Drug Administration.

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