

**Norfloxacin Cas No. : 70458-96-7**

Norfloxacin is used to treat a variety of bacterial infections. This medication belongs to a class of drugs called quinolone antibiotics. It works by stopping the growth of bacteria. This antibiotic treats only bacterial infections. It will not work for virus infections (e.g., common cold, flu). Unnecessary use or overuse of any antibiotic can lead to its decreased effectiveness.

Active Pharmaceuticals Ingredients Manufacturers



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**Taj Pharmaceuticals Ltd.****Norfloxacin****CAS No. : 70458-96-7****Systematic (IUPAC) name**

1-ethyl-6-fluoro-4-oxo-7-piperazin-1-yl-1H-quinoline-3-carboxylic acid

**Identifiers**

ATC code J01MA06 S01AX12

PubChem 4539

DrugBank APRD00469

**Chemical data**Formula C<sub>16</sub>H<sub>18</sub>FN<sub>3</sub>O<sub>3</sub>

Mol. mass 319.331 g/mol

**Pharmacokinetic data**

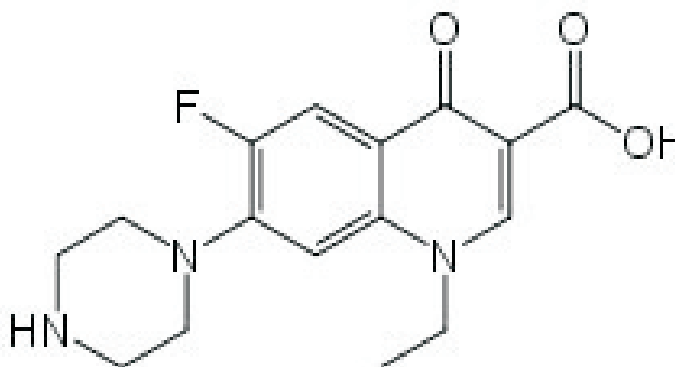
Bioavailability 30 to 40%

Protein binding 10 to 15%

Metabolism Hepatic

Half life 3 to 4 hours

Excretion Renal and fecal

**WARNING**

This medication may rarely cause tendon damage (e.g., tendinitis, tendon rupture) during or after treatment. Your risk for tendon problems is greater if you are over 60 years of age, if you are taking corticosteroids (such as prednisone), or if you have had a kidney, heart or lung transplant. Stop exercising, rest, and seek immediate medical attention if you develop joint/muscle/tendon pain or swelling.

**USES**

Norfloxacin is used to treat a variety of bacterial infections. This medication belongs to a class of drugs called quinolone antibiotics. It works by stopping the growth of bacteria.

This antibiotic treats only bacterial infections. It will not work for virus infections (e.g., common cold, flu).

Unnecessary use or overuse of any antibiotic can lead to its decreased effectiveness.

**HOW TO USE**

Take this medication by mouth, usually twice a day, at least 1 hour before or 2 hours after a meal or dairy products (e.g., milk, yogurt). Take with a full glass of water (8 ounces or 240 milliliters). The dosage is based on your medical condition and response to treatment. Drink plenty of fluids while taking this medication unless your doctor tells you otherwise.

Take this medication at least 2 hours before or 2 hours after taking any drugs that contain magnesium, aluminum, or calcium. Some examples include quinapril, certain forms of didanosine (chewable/dispersible buffered tablets or pediatric oral solution), vitamins/minerals, and antacids. Follow the same instructions if you take calcium-enriched juice, bismuth subsalicylate, sucralfate, iron, and zinc. These medications/products bind with norfloxacin and prevent its full absorption.



Taj Pharmaceuticals Ltd.  
**Norfloxacin**

CAS No 70458-96-7

Antibiotics work best when the amount of medicine in your body is kept at a constant level. It is important not to miss a dose. To help you remember, take this medication at the same times every day. Continue to take this medication until the full prescribed amount is finished, even if symptoms disappear after a few days. Stopping the medication too early may allow bacteria to continue to grow, which may result in a return of the infection.

### SIDE EFFECTS

- # Nausea, diarrhea, dizziness, lightheadedness, or headache may occur. If any of these effects persist or worsen, tell your doctor or pharmacist promptly.
- # Tell your doctor immediately if any of these unlikely but serious side effects occur: mental/mood changes (e.g., anxiety, confusion, hallucinations, depression, rare thoughts of suicide), shaking (tremors), sunburn (sun sensitivity).
- # Tell your doctor immediately if any of these rare but very serious side effects occur: unusual bruising/bleeding, signs of a new infection (e.g., new/persistent fever, persistent sore throat), seizures, unusual change in the amount of urine, signs of liver problems (e.g., unusual tiredness, stomach/abdominal pain, persistent nausea/vomiting, yellowing eyes/skin, dark urine), vision changes.
- # Seek immediate medical attention if any of these rare but very serious side effects occur: severe dizziness, fainting, fast/irregular heartbeat.
- # Norfloxacin may rarely cause serious nerve problems that may be reversible if identified and treated early. Seek immediate medical attention if you develop any of the following symptoms: pain/numbness/burning/tingling/weakness in any part of the body, changes in how you sense touch/pain/temperature/body position/vibration.

### PRECAUTIONS

Before taking norfloxacin, tell your doctor or pharmacist if you are allergic to it; or to other quinolone antibiotics such as ciprofloxacin, gemifloxacin, levofloxacin, moxifloxacin, or ofloxacin; or if you have any other allergies. Before using this medication, tell your doctor or pharmacist your medical history, especially of: low levels of potassium or magnesium in the blood, certain metabolic disorder (G6PD deficiency), diabetes, family history of a certain heart problem (QT prolongation in the EKG), heart problems (e.g., slow/fast/irregular heartbeat, heart failure, recent heart attack), joint/tendon problems (e.g., tendonitis, bursitis), kidney disease, certain muscle problem (myasthenia gravis), nervous system disorder (e.g., peripheral neuropathy), seizure disorder, conditions that increase your risk of seizures (e.g., brain/head injury, brain tumors, cerebral atherosclerosis). This medication may rarely cause serious changes in blood sugar levels, especially if you have diabetes. Watch for symptoms of high blood sugar including increased thirst and urination. Also watch for symptoms of low blood sugar such as nervousness, shakiness, fast heartbeat, sweating, or hunger. Check your blood sugar regularly as directed by your doctor and report any changes. If you experience symptoms of low blood sugar, you may raise your blood sugar by using glucose tablets/gel or eating a quick source of sugar such as table sugar, honey, or candy, or drinking fruit juice or non-diet soda. Tell your doctor immediately about the reaction and the use of this product. To help prevent low blood sugar, eat meals on a regular schedule, and do not skip meals. This drug may make you dizzy or lightheaded. Use caution while driving, using machinery, or taking part in any activity that requires alertness. Limit alcoholic beverages. This medication may make you more sensitive to the sun. Avoid prolonged sun exposure, tanning booths, and sunlamps. Use a sunscreen and wear protective clothing when outdoors.

### MISSED DOSE

If you miss a dose, take it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

### STORAGE

Store at room temperature at 77 degrees F (25 degrees C) away from light and moisture. Brief storage between 59-86 degrees F (15-30 degrees C) is permitted. Do not store in the bathroom. Keep all medicines away from children and pets.



## DOSAGE

Take this medication by mouth, usually twice a day, at least 1 hour before or at least 2 hours after a meal or dairy products (e.g., milk, yogurt). Take with a full glass of water (8 ounces or 240 milliliters). Drink plenty of fluids while taking this medication unless your doctor tells you otherwise. The dosage is based on your medical condition. Take this medication 2 hours before or 2 hours after taking any products containing magnesium, aluminum, or calcium. Some examples include quinapril, certain forms of didanosine (chewable/dispersible buffered tablets or pediatric oral solution), vitamins/minerals, and antacids. Calcium-enriched juices, sucralfate, bismuth subsalicylate, iron, and zinc are also included. These products bind with norfloxacin preventing its full absorption. Antibiotics work best when the amount of medicine in your body is kept at a constant level. Therefore, take this drug at evenly spaced intervals. Continue to take this medication until the full-prescribed amount is finished even if symptoms disappear after a few days. Stopping the medication too early may allow bacteria to continue to grow, which may result in a relapse of the infection. Inform your doctor if your condition persists or worsens.

Tablets Norfloxacin should be taken at least one hour before or at least two hours after a meal or ingestion of milk and/or other dairy products. Multivitamins, other products containing iron or zinc, antacids containing magnesium and aluminum, sucralfate, chewable/buffered tablets or the pediatric powder for oral solution, should not be taken within 2 hours of administration of norfloxacin. Tablets Norfloxacin should be taken with a glass of water. Patients receiving Norfloxacin should be well hydrated

## DRUG DESCRIPTION

# Norfloxacin is a synthetic, broad-spectrum antibacterial agent for oral administration. Norfloxacin, a fluoroquinolone, is 1-ethyl-6-fluoro-1,4-dihydro-4-oxo-7-(1-piperazinyl)-3quinolinecarboxylic acid.

# Norfloxacin is a white to pale yellow crystalline powder with a molecular weight of 319.34 and a melting point of about 221°C. It is freely soluble in glacial acetic acid, and very slightly soluble in ethanol, methanol and water.

# Norfloxacin is available in 400-mg tablets. Each tablet contains the following inactive ingredients: cellulose, croscarmellose sodium, hydroxypropyl cellulose, hydroxypropyl methylcellulose, magnesium stearate, and titanium dioxide.

# Norfloxacin, a fluoroquinolone, differs from non-fluorinated quinolones by having a fluorine atom at the 6 position and a piperazine moiety at the 7 position.

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**Note /Government Notification:** These chemicals are designated as those that are used in the manufacture of the controlled substances and are important to the manufacture of the substances. For any (Control Substance) products Import and Export \*\*\* subjected to your country government laws /control substance ACT.

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The Controlled Substances Act (CSA) was enacted into law by the Congress of the United States as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.[1] The CSA is the federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain substances is regulated. The Act also served as the national implementing legislation for the Single Convention on Narcotic Drugs

This document plus the full buyer/ prescribing information, prepared for health professionals can be found at:

<http://www.tajapi.com>

or by contacting the sponsor, Taj Pharmaceuticals Limited., at:  
91 022 30601000.

This leaflet was prepared by  
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