

NORFOX TABLET

Norfloxacin (400mg)

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What is Norfox used for?

Norfox contains the active ingredient norfloxacin. It is used for the treatment of urinary tract and gastrointestinal infections, gonorrhea (sexually transmitted infection) and prostate inflammation.

How does Norfox work?

Norfox is a quinolone antibiotic that kills susceptible bacteria which is the cause of infections.

Before you take Norfox

- When must you not take it

Do not take Norfox if you:

- are still a growing adolescent, pregnant or breastfeeding
- are allergic to norfloxacin and/or any antibiotics that belong to the group of quinolone.

If you are not sure, talk to your doctor or pharmacist before taking Norfox.

- Before taking Norfox

You should tell your doctor if you have:

- kidney and/or liver impairment
- ~~damaged central nervous system~~

- seizures or any other condition that causes fits
- a condition causing tired and weak muscles, called myasthenia gravis

Tell your healthcare providers if you have been diagnosed with an enlargement or “bulge” of a large blood vessel (aortic aneurysm or large vessel peripheral aneurysm).

Tell your healthcare providers if you have experienced a previous episode of aortic dissection (a tear in the aorta wall).

Tell your healthcare providers if you have a family history of aortic aneurysm or aortic dissection or other risk factors or predisposing conditions (e.g. connective tissue disorders such as Marfan syndrome, or vascular Ehlers-Danlos syndrome, or vascular disorders such as Takayasu arteritis, giant cell arteritis, Behcet’s disease, high blood pressure, or known atherosclerosis).

You should not take fluoroquinolone antibacterial medicines, including Norfox, if you have experienced any serious adverse reaction in the past when taking a fluoroquinolone (see section Things to be careful of and Side effects). In this situation, you should inform your healthcare providers as soon as possible.

- Taking other medicines

Before you consume Norfox, do tell your doctor or pharmacist if you have recently taken, are taking or intend to take any other medications and supplements that may interact with Norfox, such as:

- theophylline (used to treat lung disease)
- multivitamins and mineral supplements
- antacids containing aluminum or magnesium
- anti-coagulant e.g. warfarin

Consuming milk or dairy products concurrently with Norfox should be avoided as the absorption of this medicine may be reduced.

How to take Norfox

- How much to take

The usual dose is 1 tablet twice daily, to be consumed orally, but this may vary according to your infection. Dose adjustment is needed in patients with kidney impairment.

You should not take Norfox without consulting your doctor.

- When to take it

Food may decrease the rate and/or extent of Norfox absorption. To ensure optimal efficacy, Norfox is taken 1 hour before or 2 hours after a meal.

- How long to take it

The recommended duration of treatment depends on the severity and type of infection that you have. Please refer to your doctor for further advice.

Always complete the full course of an antibiotic as instructed by your doctor.

- What if you forget to take

Take the missed dose as soon as you remember. Skip the missed dose if it is almost time for your next scheduled dose. Do not take extra tablet to make up for the missed dose.

- What if you take too much (overdose)

If you take too much Norfox, call your healthcare provider or seek medical help immediately.

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While you are taking Norfox

- What must you do

Ensure adequate fluid intake during Norfloxacin treatment to avoid risk of having crystals in the urine.

Norfox may cause your skin to become more sensitive to sunlight than usual. Protect your skin by using sunscreen particularly if you are exposed to strong sunlight for a prolonged period of time.

Take your medicine exactly as your doctor has told you. Tell your healthcare professionals about all the medications that you are taking.

- What must you NOT do

Do not forget to take any dose of antibiotic as this may cause your medicine to be ineffective.

Do not take any new medicines without consulting your doctor.

Do not give Norfox to anyone else, even if they have the same symptoms or condition as yours.

- What to be careful of

Pregnancy and lactation

The safety of norfloxacin in pregnant and nursing mothers have not been established. This medicine should only be taken if the benefits outweigh the risks. Consult your doctor before taking this medicine.

Driving and using machineries

This medicine may cause dizziness. Do not operate machineries or drive while on this medicine.

Things to be careful of:

If you feel sudden, severe pain in your abdomen, chest or back, go immediately to the emergency department.

Prolonged, disabling and potentially irreversible serious side effects

Fluoroquinolone antibacterial medicines, including Norfox, have been associated with very rare but serious side effects, some of them being long lasting (continuing months or years), disabling or potentially irreversible.

Stop taking your fluoroquinolone antibiotic and contact your healthcare providers immediately if you have the following signs of a side effect:

- Tendon pain or swelling, often beginning in the ankle or calf. If this happens, rest the painful area until you can see your healthcare providers.
- Pain in your joints or swelling in your shoulder, arms, or legs.
- Abnormal pain or sensations (such as persistent pins and needles, tingling, tickling, numbness, or burning), weakness in your body, especially in the legs or arms, or difficulty walking.
- Severe tiredness, depressed mood, anxiety, problems with your memory, or severe problems sleeping.
- Changes in your vision, taste, smell, or hearing.

Tell your healthcare providers if you have had one of the above effects during or shortly after taking a fluoroquinolone – this means you should avoid them in the future. You and your healthcare providers will decide on continuing the treatment considering also an antibiotic from another class.

Tendinitis and tendon rupture

Pain and swelling in the joints and inflammation or rupture of tendons may occur rarely. Your risk is increased if you are elderly (above 60 years of age), have received an organ transplant, have kidney problems or if you are being treated with corticosteroids. Inflammation and ruptures of tendons may occur within the first 48 hours of treatment and even up to several months after stopping of Norfox therapy. At the first sign of pain or inflammation of a tendon (for example in your ankle, wrist, elbow, shoulder or knee), stop taking Norfox, contact your healthcare providers and rest the painful area. Avoid any unnecessary exercise as this

might increase the risk of a tendon rupture.

Peripheral neuropathy

You may rarely experience symptoms of nerve damage (neuropathy) such as pain, burning, tingling, numbness and/or weakness especially in the feet and legs or hands and arms. If this happens, stop taking Norfox and inform your healthcare providers immediately in order to prevent the development of potentially irreversible condition.

Side-effects

Common side effects include nausea, vomiting, diarrhoea, rash, heartburn, dizziness, headache and abdominal pain/cramps.

Fluoroquinolones have been reported to cause serious side effects involving tendons, muscles, joints, and the nerves – in a small proportion of patients, these side effects caused long-lasting or permanent disability (see section Before you start to use it and Things to be careful of).

You may report any side-effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my (Consumers → Reporting Side-effects to Medicines (ConSERV) or Vaccine (AESI).

Storage & disposal of Norfox

Storage

Keep this medicine out of reach of children. Store at room temperature below 30°C and protect from light.

Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

NORFOX TABLET

Norfloxacin (400mg)

Product description

- What does it look like?

Norfox is a white long, biconvex, and scored film-coated tablet, embossed with 'N/X' and '400' on each side.

- Ingredients

- Each capsule contains 400 mg norfloxacin as active substance.
- Excipients include magnesium stearate, microcrystalline cellulose, talcum, lactose and sodium starch glycolate

- MAL number

MAL 19930497AZ

Manufacturer

The United Drug (1996) Co., Ltd.
208 Romklao Road, Minburi,
Bangkok 10510, Thailand.

Product Registration Holder

Milrin Pharmaceutical Co. (M) S/B.
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