

NOROXIN®

400 mg film-coated tablets
Norfloxacin

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

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1. SERIOUS SIDE EFFECTS

Noroxin® belongs to a class of antibiotics called fluoroquinolones. Noroxin® can cause serious side effects. Some of these serious side effects can happen at the same time and could result in 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®.

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)
- Stop taking Noroxin® immediately and get medical help 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 can happen within hours or days of taking Noroxin®, and 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:

- 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

Changes in sensation and possible nerve damage (Peripheral Neuropathy):

Damage to the nerves in arms, hands, legs, or feet can happen in people who take fluoroquinolones, including Noroxin®.

Stop taking Noroxin® immediately and talk to your healthcare provider right away if you get any of the following symptoms of peripheral neuropathy in your arms, hands, legs, or feet: pain, numbness, burning, weakness, tingling

Noroxin® may need to be stopped to prevent permanent nerve damage.

Central Nervous System (CNS) effects:

Seizures have been reported in people who take fluoroquinolone antibacterial medicines, including Noroxin®. Tell your healthcare provider if you have a history of seizures before you start taking Noroxin®. CNS side effects may happen as soon as after taking the first dose of Noroxin®.

Stop taking Noroxin® immediately and talk to your healthcare provider right away if you get any of these side effects, or other changes in mood or behavior:

- Seizures
- trouble sleeping
- hear voices, see things, or sense things
- nightmares that are not there (hallucinations)
- feel lightheaded or dizzy
- feel restless
- feel more suspicious (paranoia)
- tremors
- suicidal thoughts or acts
- feel anxious or nervous
- headaches that will not go away, with or without blurred vision
- confusion
- depression

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. Tell your healthcare provider if you have a history of myasthenia gravis before you start taking Noroxin®. Call your healthcare provider right away if you have any worsening muscle weakness or breathing problems.

2.WHAT NOROXIN® IS AND WHAT IT IS USED FOR

Noroxin® belongs to a group of antibiotics called quinolones. It is used to treat some bacterial infections,

such as:

- urinary tract infections (uncomplicated urinary tract infections including cystitis and complicated urinary tract infections)
- sexually transmitted diseases (uncomplicated urethral and cervical gonorrhea due to *Neisseria gonorrhoea*)
- Prostatitis (due to *Escherichia coli*)

Urinary tract infections are caused by the presence of bacteria in the urinary system. The bacteria often come from the intestines where they are necessary for normal function.

In women, the most common infection involves the bladder and is called cystitis. In men, the infection may involve the prostate which is called prostatitis. In both men and women, the bacteria may travel up to the kidneys and infect them.

The symptoms of a urinary tract infection may include an urge to urinate frequently and in small amounts, and painful burning when passing urine. Urinary tract infections should be treated to avoid the kidneys being infected.

Stop taking Noroxin® works by killing the bacteria causing the infection. Your doctor may have prescribed Noroxin® for another reason. Ask your doctor if you have any questions about why Noroxin® has been prescribed for you.

Noroxin® should not be used in patients with acute exacerbation of chronic bronchitis, acute uncomplicated cystitis, and sinus infections, if there are other treatment options available.

Noroxin® should not be used as the first choice of antibacterial medicine to treat lower respiratory tract infections caused by a certain type of bacteria called *Streptococcus pneumoniae*.

3. BEFORE YOU TAKE NOROXIN®

Noroxin® tablets are not for use in children.

Do not take Noroxin® if

- You have an allergy to Noroxin®, other quinolone antibiotics or any of the ingredients listed at the end of this leaflet. Symptoms of an allergic reaction to Noroxin® may include itchiness, hives, swelling of the face, lips, tongue, and/or throat (which may cause difficulty in breathing or swallowing), muscle pain or tenderness, or joint pain.
 - You are pregnant or breast-feeding.
 - You have had pain, inflammation or rupture of tendons after taking quinolone antibiotics.
 - If you are not sure whether you should start taking Noroxin®, talk to your doctor.
- Do not give Noroxin® to children less than 18 years of age, unless advised by the doctor. The safety of Noroxin® has not been adequately studied in these people.

Take special care with Noroxin®

Check with your doctor or pharmacist before taking your medicine if:

- you intend to become pregnant or intend to breast-feed.
- you have or have had any medical conditions, especially the following:

- kidney disease
- nerve problems: Noroxin® should not be used in patients who have a history of a nerve problem called peripheral neuropathy
- seizures or fits or a history of them
- myasthenia gravis, a disease that causes muscle weak-

ness. Noroxin® should not be used in patients with a known history of myasthenia gravis.

- heart rhythm problems, have salt imbalance in the blood (especially low level of potassium or magnesium in the blood) have a weak heart (heart failure), have a history of heart attack (myocardial infarction), you are female or elderly or you are taking other medicines that result in abnormal ECG changes
- if you suffer from psychiatric disorders, hallucinations and/or confusion

- you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.

- you or any member of your family suffers from a deficiency disorder where patients become anaemic after taking certain drugs (glucose-6-phosphate dehydrogenase, G-6-PD deficiency) (symptoms of anaemia include paleness and tiredness)

- your eyesight becomes impaired or if your eyes seem to be otherwise affected, consult an eye specialist immediately.

- you may experience symptoms of neuropathy such as pain, burning, tingling, numbness and/or weakness. If this happens, stop taking Noroxin® tablets and contact your doctor immediately.

- pain, inflammation or rupture of tendons, particularly around the ankles may occur with this class of antibiotics, especially if you are older or if you are taking corticosteroids at the same time. If you experience tendon pain or signs of inflammation of the Achilles tendon stop taking your medicine and contact your doctor and rest the affected limb.

If you are not sure talk to your doctor or pharmacist before taking Noroxin®.

- If you have been diagnosed with an enlargement or "bulge" of a large blood vessel (aortic aneurysm or large vessel peripheral aneurysm)
- If you have experienced a previous episode of aortic dissection (a tear in the aorta wall).

- 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).

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

Taking Noroxin® with other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Some medicines and Noroxin® may interfere with each other. These include:

- Nitrofurantoin, another antibiotic used to treat urinary tract infections
- certain medicines that are metabolized by a specific enzyme in the liver such as: caffeine, cizapride, ropinirole, tacrine, theophylline, tizanidine
- theophylline, a medicine used to treat asthma
- cyclosporin, a medicine commonly used in patients who have received organ transplants
- warfarin, a medicine used to treat blood clots
- probenecid, a medicine used to treat gout
- gliclazide, a medicine used to treat diabetes
- non-steroidal anti-inflammatory drugs, known as NSAIDs, including ibuprofen (a medicine for rheumatism)

- erythromycin, another antibiotic used to treat & in some cases prevent infection

- cizapride, a medicine used to treat discomfort due to the stomach acid flowing the wrong way up the oesophagus (also called the food pipe)

- some medicines used to treat irregular heartbeats such as sotalol, amiodarone, quinidine, and procainamide
 - antipsychotics, a group of medicines used to treat certain mental & emotional conditions
 - triecyclic antidepressants, a group of medicines used to treat depression such as amitriptyline & nortriptyline
- These medicines may be affected by Noroxin®, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Some medicines may interfere with the absorption of Noroxin®. These include:

- iron or zinc supplements, and multivitamins containing them
- antacids used for indigestion
- sucralfate, a medicine used to treat stomach ulcers
- didanosine (ddI), a medicine used to treat HIV infection.

You can still take these medicines while you are taking Noroxin®. However, you must take Noroxin® at least 2 hours before or 4 hours after taking any of these medicines to make sure there is no problem with absorption.

Pregnancy, breast-feeding and fertility

If you are pregnant, planning a family or breast-feeding, tell your doctor before taking this medicine, as it is not recommended for use under these conditions.

Driving and using machines

Your reactivity may be altered so that your ability to drive or operate machinery is impaired, especially at the start of treatment, on increasing the dosage or when switching medication and in conjunction with alcohol.

4. HOW TO TAKE NOROXIN®

Always take Noroxin® exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Swallow the tablets whole with a glass of water.
- Take Noroxin® on an empty stomach, at least one hour before food or two hours after food.
- Multivitamins, products containing iron or zinc, antacids or sucralfate should not be taken at the same time as this medicine. This medicine should be taken either 2 hours before or least 4 hours after such products.

How much to take

Take Noroxin® only when prescribed by your doctor.

Your doctor will tell you how many tablets you need to take each day.

The usual dose of Noroxin® is one tablet (400 mg norfloxacin) twice a day.

In case of patients with kidney problems: If you suffer from severe renal impairment, your doctor may adjust your dosage. The recommended dose is 1 tablet (400 mg norfloxacin) once daily.

Preferably the tablets should be taken in the morning and evening. If you only take a single daily dose, always take this at the same time of day.

If you take more Noroxin® than you should

Tell a doctor or go to the nearest hospital casualty

department straight away. Do not drive to the hospital, get somebody else to take you or call for an ambulance. Take the medicine pack with you. This is so the doctor knows what you have taken.

How long to take Noroxin®

Continue taking Noroxin® until you finish the pack or as recommended by your doctor.

- For treatment of urinary tract infections: The length of treatment may vary from three to ten days.

- To help stop frequent urinary tract infections from coming back: You may need to take Noroxin® for up to 12 weeks.
- For infections of the stomach or intestines: Usually for five days.

Do not skip any doses of Noroxin®, or stop taking it, even if you begin to feel better, until you finish your prescribed treatment unless:

- You have nerve problems (see serious side effects)
- You have central nervous system problems (see serious side effects)

If you forget to take Noroxin®

If you miss a dose, take your normal dose as soon as you remember.

If it is almost time for your next dose, skip the missed dose and continue with the regular dosing schedule. Do not take a double dose to make up for a forgotten tablet.

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

5. POSSIBLE SIDE EFFECTS

Like all medicines, Noroxin® can cause side effects, although not everybody gets them.

Stop taking Noroxin® and see a doctor straight away, if you notice any of the following serious side effects - you may need urgent medical treatment:

- watery and severe diarrhoea, which may also be bloody
- a rash together with very dry eyes and dry mouth,
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- if you have skin rash accompanied by fever and feeling unwell

- sudden and severe pain or swelling of muscles, joints or tendons

- severe and sudden onset of pinkish, itchy swellings on the skin, also called hives or nettle rash (not caused by sunburn)

- convulsions
- passing little or no urine, pain or tenderness around kidney area
- inflammation of the liver with jaundice (yellowing of the skin or whites of the eyes) commonly occurs. Stop treatment and contact your doctor if you experience signs and symptoms of liver problems such as loss of appetite, jaundice, dark urine, itching or sensitivity to pressure in the abdominal cavity.

Other side effects include:

- Please tell your doctor if any of the following gets serious or lasts longer than a few days.
- Most common side effects:
- diarrhoea
- nausea
- dizziness
- diarrhoea
- heartburn
- headache
- stomach (abdominal) cramping

- weakness

Other side effects:

- rhabdomyolysis (breakdown of the muscle tissue with muscle pain)
- anaemia (paleness and tiredness), sometimes associated with Glucose-6-phosphatedehydrogenase deficiency, due to a red cell loss
- tiredness, changes of mood, a tingling sensation, sleeplessness, sleep disturbances, depression, feeling of anxiety, restlessness, irritability, exaggerated sense of well-being, disorientation, hallucinations, confusion
- visual disturbance, increased production of tears
- ringing in the ears
- bleeding into the skin with inflammation of blood vessels.

- inflammation of the pancreas (symptoms include abdominal pain, fever, being sick)
- loss of appetite
- inflammation of the kidneys (symptoms may include blood in the urine, decreased urine)
- skin reactions to sunlight
- worsening of a condition called myasthenia gravis which causes muscle weakness
- vaginal thrush (itching, soreness or burning of the vagina)

- reduced number of white blood cells "leucocytes" [leucopenia] or "neutrophils" [neutropenia], increased number of certain white blood cells "eosinophils" [eosinophilia], which may cause sore throat and mouth, increased frequency of infections
- reduced number of blood platelets [thrombocytopenia], reduced volume of the red blood cells in the blood [hematocrit], reduced blood clotting ability, which may cause prolonged bleeding after injury
- increased liver enzymes
- effects on the kidney which cause pain and discomfort when passing water (crystalluria)

The mental health side effects:

- Disturbances in attention,
- Disorientation,
- Agitation,
- Nervousness,
- Memory impairment,
- Delirium.

-Blood Glucose Disturbances: hypoglycaemic coma

Noroxin® should be discontinued immediately if a patient reports any nervous system side effects, including psychiatric adverse reactions, or blood glucose disturbances and switch to a non-fluoroquinolone antibacterial drug.

Serious side effects (rare):

- central nervous system effects (lightheadedness, seizure, tremors, confusion, feeling restless)
- serious allergic reactions (hives, difficulty breathing or swallowing, swelling of the lips, tongue, face, throat)
- tightness/hoarseness, rapid heartbeat, yellowing of the skin or eyes)
- skin rash
- serious heart rhythm changes (QTc prolongation and torsade de pointes)
- intestine infection (pseudomembranous colitis)
- peripheral neuropathy (serious nerve damage) is an identified risk factor of fluoroquinolone drugs taken by mouth or by injection. (Peripheral neuropathy symptoms in the arms or legs such as pain, burning, tingling, numbness, or a change in sensation to light touch, pain, or temperature)

Peripheral neuropathy can occur at any time during treatment with fluoroquinolones (may occur soon after these drugs are taken) and can last for month to years after the drug is stopped or be permanent. If you develop symptoms of peripheral neuropathy, stop Noroxin® and consult with your healthcare provider right away.

After finishing Noroxin®

Tell your doctor immediately if you notice any of the following side effects, particularly if they occur several months after stopping treatment with Noroxin®:

- severe abdominal cramps or stomach cramps
- watery and severe diarrhoea, which may also be bloody
- fever, in combination with one or both of the above

These are rare but serious side effects. Noroxin® can cause bacteria, which are normally present in the bowel and normally harmless, to multiply and therefore cause the above symptoms. You may need urgent medical attention. However, this side effect is rare.

Do not take any diarrhea medicine without first checking with your doctor.

6. HOW TO STORE NOROXIN®

Keep out of the reach and sight of children.

Do not store above 30°C.

Store in the original packaging.

Do not use Noroxin® tablets after the expiry date stated on the carton and the blister. The expiry date refers to the last day of that month.

7. FURTHER INFORMATION

What Noroxin® contains

Noroxin® film-coated tablets contain 400 mg of norfloxacin.

Excipients: Microcrystalline cellulose, croscarmellose sodium, magnesium stearate, hydroxypropylmethylcellulose, hydroxy-propylcellulose, titanium dioxide, carnauba wax.

What Noroxin® looks like and contents of the pack

Noroxin® tablets are white, film-coated, oval-shaped biconvex tablets, one side scored, the other engraved "ALX N400".

Noroxin® is available in packs of 14 tablets.

<p>This is a medicament</p> <p>- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.</p> <p>- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.</p> <p>- The doctor and the pharmacist are the experts in medicines, their benefits and risks.</p> <p>- Do not try yourself interrupt the period of treatment prescribed.</p> <p>- Do not repeat the same prescription without consulting your doctor.</p> <p>- Keep all medicaments out of reach of children.</p>	<p>Council of Arab Health Ministers Union of Arab Pharmacists</p>
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Marketing Authorization Holder And Final Batch Release:

ALGORITHM S.A.L., Zouk Mosbeh, Lebanon.

Manufacturer:

ALGORITHM S.A.L., Zouk Mosbeh, Lebanon.

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