

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Roxin. It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Roxin against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What Roxin is used for

Roxin contains norfloxacin as the active ingredient. It belongs to a group of antibiotics called quinolones. These medicines work by killing the bacteria that is causing infection.

Roxin is an antibiotic used to treat:

- urinary tract infections
- gastrointestinal infections.

Ask your doctor if you have any questions about why Roxin has been prescribed for you.

Your doctor may have prescribed this medicine for another reason.

Roxin is available only with a doctor's prescription.

There is no evidence that it is addictive.

Before you take it

When you must not take it

Do not take Roxin if you are allergic to medicines containing:

- norfloxacin
- other quinolone antibiotics including nalidixic acid
- any of the ingredients listed at the end of this leaflet.

Do not take Roxin if you are pregnant, or intend to become pregnant.

Roxin may affect your developing baby if you take it during pregnancy.

Do not take this medicine if you are breastfeeding or intend to breastfeed.

The active ingredient in Nufloxib may pass into breast milk and may affect your baby.

Do not give Roxin to children and to pre-pubertal adolescents, as there have been no studies of its effects in this age group.

Do not take Roxin if the expiry date (Exp.) printed on the pack has passed.

Do not take Roxin if the packaging shows signs of tampering or the tablets do not look quite right.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you are breastfeeding or wish to breastfeed.

Roxin should not be used during pregnancy or while breast-feeding.

Tell your doctor if you have, or have had, any medical conditions, especially the following:

- Kidney problems
- Fits or seizures
- Myasthenia gravis (a condition in which the muscles become weak and tire easily)
- Glucose-6-phosphate dehydrogenase deficiency
- Heart rhythm problems
- Arthropathy
- Crystalluria
- Vision disorders
- Tendon inflammation
- Diabetes
- Risk of aortic aneurysm and dissection.

If you have not told your doctor about any of the above, tell them before you start taking Roxin.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may be affected by Roxin, or may affect how well it works. These include:

- theophylline (such as Nuelin), a medicine used to treat asthma
- warfarin (such as Coumadin, Marevan), a medicine used to prevent blood clots
- phenindione (such as Dindevan), a medicine also used to prevent blood clots
- probenecid (Pro-Cid), a medicine used to treat gout
- nitrofurantoin (Ralodantin, Macrochantin), a medicine used to treat urinary tract infections
- cyclosporin (Neoral, Sandimmun, Cysporin), a medicine used to suppress the immune system
- certain drugs that are metabolised by a specific enzyme: clozapine, ropinirole, tacrine, tizanidine
- glibenclamide, a medicine used to treat diabetes
- metronidazole (such as Flagyl, Metrogyl), a medicine used to treat various types of bacterial infections
- non-steroidal anti-inflammatory drugs (NSAIDs), medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis
- erythromycin, a medicine used to treat infections
- cisapride, a medicine used to treat gastric reflux, usually experienced as heartburn
- some medicines used to treat irregular heart beats such as sotalol, amiodarone, quinidine and procainamide
- antipsychotics, medicines used to treat certain mental and emotional conditions

- tricyclic antidepressants, medicines used to treat depression such as amitriptyline and nortriptyline.

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

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

- iron or zinc supplements, and multivitamins containing them
- calcium preparations
- antacids (such as Mylanta, AluTab, Gastrogel) used for indigestion
- sucralfate (Ulcyste, Carafate), a medicine used to treat stomach ulcers
- didanosine (Videx and Videx EC), a medicine used to treat HIV infections.

You can still take these medicines while you are taking Roxin, however, you must take Roxin at least 2 hours before or 2 hours after taking them to make sure there is no problem with absorption.

Roxin may prolong the effect of coffee and other drinks containing caffeine.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Roxin.

How to take it

How much to take

Follow all directions given to you by your doctor and pharmacist carefully.

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

The usual dose is one tablet twice a day.

How to take it

Swallow the tablets with a glass of water.

Take Roxin on an empty stomach, one hour before or two hours after food.

Food can interfere with the absorption of Roxin.

Do not take Roxin at the same time as taking iron or zinc supplements (or any multivitamins containing them), antacids, didanosine or sucralfate.

Taking Roxin at the same time or even within two hours of taking these can interfere with the absorption of Roxin, so that the chance of Roxin fighting the infection won't be as good.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

Do not take a double dose to make up for the dose you missed.

If you are not sure what to do, ask your doctor or pharmacist.

How long to take it

Keep taking Roxin until you finish the pack, or for as long as your doctor recommends.

Do not stop taking Roxin, even if you feel better after a few days, unless advised by your doctor.

Your infection may not clear completely if you stop taking this medicine too soon.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Roxin. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking it

Things you must do

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Roxin, especially if you are about to start taking any new medicines.

Tell your doctor if you become pregnant while taking Roxin.

Tell your doctor or pharmacist immediately if you get severe diarrhoea.

Do this even if it occurs several weeks after you have stopped taking Roxin.

Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care.

Do not take any diarrhoea medicine without checking with your doctor.

Drink plenty of water or fluids while you are taking Roxin.

This will help prevent crystals forming in the urine, leading to kidney problems. This side effect is very rare.

Things you must not do

Do not take Roxin to treat any other conditions unless your doctor tells you to.

Do not give Roxin to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how Roxin affects you.

This medicine may cause drowsiness, dizziness or lightheadedness in some people. If any of these occur, do not drive, operate machinery or do anything else that could be dangerous while taking Roxin.

Protect your skin when you are in the sun, especially between 10 am and 3 pm. If outdoors, wear protective clothing and use a 30+ sunscreen.

Roxin may cause your skin to be much more sensitive to sunlight than it is normally. This may cause a skin rash, itching, redness or severe sunburn.

If your skin does appear to be burning, stop taking Roxin and tell your doctor.

Try not to consume large amounts of caffeine while you are taking Roxin.

Roxin may increase the chance of you getting side effects from caffeine, such as sleeplessness, anxiety, tremor, increased heartbeat and headache. Caffeine is contained within coffee, tea, cola and energy drinks.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Roxin.

Like all other medicines, Roxin may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- nausea, upset stomach, stomach pain
- headache
- dizziness
- disturbances to vision
- rash
- tiredness, changes in sleep pattern
- vaginal thrush - sore and itchy vagina or discharge.

These side effects are usually mild.

Tell your doctor as soon as possible if you notice any of the following:

- increased sensitivity of the skin to the sun, with symptoms of sunburn (redness, blistering or itching) happening more quickly than usual
- confusion, depression, hallucinations
- bleeding or bruising more easily than usual
- signs of anaemia such as tiredness, being short of breath and looking pale
- numbness or tingling in the fingers or toes
- worsening of the symptoms of myasthenia gravis
- decreased feeling or sensitivity, especially in the skin
- changes in your hearing.

These are serious side effects. You may need urgent medical attention. Serious side effects are rare.

If any of the following happen, stop taking Roxin and tell your doctor immediately, or go to Accident and Emergency at the nearest hospital:

- severe abdominal cramps or stomach cramps
- watery and severe diarrhoea, which may also be bloody
- skin rash, itching or hives or peeling or blistering of the skin
- asthma, wheezing or shortness of breath
- swelling of the face, lips tongue or throat that may cause difficulty in swallowing or breathing
- yellowing of the skin or eyes
- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- sudden and severe pain or swelling of the muscles, joints or tendons
- seizures, convulsions or fits
- passing little or no urine, blood in the urine.

These are very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

After you have finished taking it

Tell your doctor immediately if you notice any of the following, even if they occur

several weeks after stopping treatment with Roxin:

- 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. You may have a serious condition affecting your bowel. You may need urgent medical attention. However, these side effects are rare.

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

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking it

Storage

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Do not store Roxin or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills. Heat and dampness can destroy some medicines.

Keep this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking Roxin, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Roxin is an oval, scored, white film coated tablet marked "N | F" on one side and ">" on the other.

Available in bottles of 14 tablets.

Ingredients

Active ingredient:

Each Roxin tablet contains 400 mg of norfloxacin.

Inactive ingredients:

- microcrystalline cellulose
- croscarmellose sodium
- magnesium stearate
- Opadry AMB OY-B-28920.

Roxin tablets do not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

Arrow Pharma Pty Ltd
15 – 17 Chapel Street
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Australian registration number: AUST R 93211

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