

# APO-Norfloxacin

contains the active ingredient norfloxacin

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## Consumer Medicine Information

**For a copy of a large print leaflet, Ph: 1800 195 055**

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### What is in this leaflet

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

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

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again.

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### What this medicine is used for

The name of your medicine is APO-Norfloxacin. It contains the active ingredient norfloxacin.

Norfloxacin belongs to a group of antibiotics called quinolones. It works by killing the bacteria causing the infection.

Norfloxacin is an antibiotic used to treat some bacterial infections, such as:

- urinary tract infections
- infections of the stomach or intestines, such as traveller's diarrhoea.

Norfloxacin is also used for patients who get frequent urinary tract infections. It may help prevent these infections from coming back.

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.

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

Your doctor may have prescribed norfloxacin for another reason.

This medicine is available only with a doctor's prescription.

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### Before you take this medicine

**When you must not take it**

**Do not take this medicine if you have an allergy to:**

- any medicine containing norfloxacin
- other quinolone antibiotics (for example ciprofloxacin or ofloxacin)
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

**Do not take this medicine if you are pregnant.**

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

**Do not breastfeed if you are taking this medicine.**

Norfloxacin may pass into breast milk and there is a possibility that your baby may be affected.

**Do not give this medicine to children or to growing teenagers unless advised by the doctor.**

The safety of norfloxacin has not been adequately studied in these people.

**Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

If it has expired or is damaged, return it to your pharmacist for disposal.

**If you are not sure whether you should start taking this medicine, talk to your doctor.**

### ***Before you start to take it***

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor if you have or have had any of the following medical conditions:**

- kidney disease
- seizures or fits or a history of them
- myasthenia gravis, a muscle disease
- glucose-6-phosphate dehydrogenase deficiency
- heart rhythm problems
- arthropathy
- crystalluria
- vision disorders
- tendon inflammation
- diabetes
- risk of aortic aneurysm and dissection.

**Tell your doctor if you are pregnant or plan to become pregnant or start breastfeeding.**

Norfloxacin should not be used during pregnancy or while breastfeeding. Your doctor can discuss with you the risks and benefits involved.

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

### ***Taking other medicines***

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

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

- theophylline, used to treat asthma

- warfarin and phenindione, used to prevent blood clots
- probenecid, used to treat gout
- nitrofurantoin, used to treat urinary tract infections
- cyclosporin, used to suppress the immune system
- certain drugs that are metabolised by a specific enzyme such as clozapine, ropinirole, tacrine or tizanidine
- glibenclamide, used to treat diabetes
- metronidazole or erythromycin, used to treat infections
- non-steroidal anti-inflammatory drugs (NSAIDs), medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis
- cisapride, used to treat gastric reflux (usually experienced as heartburn)
- some medicines used to treat irregular heartbeats such as sotalol, amiodarone, quinidine or procainamide
- antipsychotics, used to treat certain mental and emotional conditions
- tricyclic antidepressants, used to treat depression such as amitriptyline and nortriptyline.

These medicines may be affected by norfloxacin or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

**Some medicines may interfere with the absorption of norfloxacin.**

**These include:**

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

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

**Norfloxacin 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 norfloxacin.

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## **How to take this medicine**

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

They may differ from the information contained in this leaflet.

**If you do not understand the instructions on the label, ask your doctor or pharmacist for help.**

### ***How much to take***

**Take norfloxacin only when prescribed by your doctor.**

**Your doctor will tell you how many tablets you need to take each day. This depends on your condition and whether you are taking any other medicines.**

**The usual dose is one tablet twice a day.**

### ***How to take it***

**Swallow the tablets with a full glass of water.**

### ***When to take it***

**Take norfloxacin doses about 12 hours apart.**

Taking norfloxacin at evenly spaced times ensures that there is a reasonably constant amount in the blood and urine. This means that the medicine will fight the infection more effectively.

**Take norfloxacin on an empty stomach, at least one hour before food or 2 hours after food, milk and/or other dairy products**

This will make sure the tablets will have a better chance of fighting the infection, because food can interfere with the absorption.

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

Taking norfloxacin at the same time or even within 2 hours of taking these can interfere with the absorption of norfloxacin.

### ***How long to take it***

**Continue taking your medicine until you finish the pack or as long as your doctor tells you.**

This medicine helps to control your condition but does not cure it. It is important to keep taking your medicine even if you feel well.

**For treatment of urinary tract infections:**

The length of treatment may vary from 3 to 10 days.

**To help stop frequent urinary tract infections from coming back:**

You may need to take norfloxacin for up to 12 weeks.

**For infections of the stomach or intestines:**

The length of treatment is usually 5 days.

**Do not stop taking your tablets because you are feeling better.**

If you do not complete the full course prescribed by your doctor, some of the bacteria causing your infection may not be killed. These bacteria may continue to grow and multiply so that your infection may not clear completely or it may return.

### ***If you forget to take it***

**If it is almost time to take your next dose, skip the dose you missed**

**and take your next dose when you are meant to.**

**Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.**

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

This may increase the chance of you getting an unwanted side effect.

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

**If you have trouble remembering to take your medicine, ask your pharmacist for some hints.**

### ***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 that you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

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## **While you are using this medicine**

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### ***Things you must do***

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking this medicine.**

**Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.**

**If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.**

It may affect other medicines used during surgery.

**If you become pregnant or start to breastfeed while taking this medicine, tell your doctor immediately.**

**If you are about to have any blood tests, tell your doctor that you are taking this medicine.**

It may interfere with the results of some tests.

**Keep all your doctor's appointments so that your progress can be checked.**

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

**If you develop severe diarrhoea, tell your doctor or pharmacist immediately. Do this even if it occurs several weeks after norfloxacin has been stopped.**

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 first checking with your doctor.

**Drink plenty of water or fluids while taking norfloxacin.**

This will help to prevent crystals forming in the urine, which can cause kidney problems. However, this is not a common problem.

### ***Things you must not do***

**Do not take this medicine to treat any other complaints unless your doctor tells you to.**

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

**Do not stop taking your medicine or lower the dosage without checking with your doctor.**

### ***Things to be careful of***

**Be careful driving or operating machinery until you know how this medicine affects you.**

Norfloxacin may cause drowsiness, dizziness or light-headedness in some people. Make sure you know how you react to norfloxacin before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If

you drink alcohol, your dizziness or light-headedness may be worse.

**Protect your skin when you are in the sun, especially between 10 am and 3 pm.**

Norfloxacin may cause your skin to be much more sensitive to sunlight than it is normally. You may get severely sunburnt even though you've only been in the sun for a short time. Symptoms of severe sunburn include redness, itching, pain, swelling or blistering.

If outdoors, wear protective clothing and use a 15+ sunscreen. If your skin does appear to be burning, stop taking norfloxacin and tell your doctor.

**Be careful if you consume large amounts of caffeine while you are taking norfloxacin.**

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

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## Side effects

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

Norfloxacin helps most people with infections of the urinary tract, stomach, or intestines but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

If you are over 65 years of age you may have an increased chance of getting side effects.

**Do not be alarmed by the following lists of side effects. You may not experience any of them.**

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

**Tell your doctor or pharmacist 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.

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

**If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your 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

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

**Tell your doctor immediately if you notice any of the following, even if they occur several weeks after stopping treatment with norfloxacin:**

- 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. Norfloxacin 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, these side effects are rare.

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

**Tell your doctor or pharmacist if you notice anything that is making you feel unwell.**

Other side effects not listed above may also occur in some people.

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## Storage and Disposal

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### **Storage**

**Keep your tablets in the blister pack until it is time to take them.**

If you take the tablets out of the pack, they may not keep well.

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

**Do not store this medicine or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.**

Heat and dampness can destroy some medicines.

**Keep it 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 this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.**

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

### **Sponsor**

Arrow Pharma Pty Ltd  
15 – 17 Chapel Street  
Cremorne VIC 3121

### **Distributor**

This medicine is distributed in Australia by:

Apotex Pty Ltd  
16 Giffnock Avenue  
Macquarie Park NSW 2113

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## Product description

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### **What it looks like**

APO-Norfloxacin 400 mg tablets are oval, scored, white film coated tablet marked "N F" on one side and ">" on the other. AUST R 155546.

Available in bottles of 14 tablets.

### **Ingredients**

This medicine contains 400 mg of norfloxacin as the active ingredient.

This medicine also contains the following:

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