

## GenRx Norfloxacin

contains the active ingredient, norfloxacin

### Consumer Medicine Information

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

#### What is in this leaflet

**Read this leaflet carefully before taking your medicine. Ask your doctor or pharmacist if you do not understand anything or are worried about taking your medicine.**

This leaflet answers some common questions about norfloxacin.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. Some more recent information on your medicine may be available. Speak to your pharmacist or doctor to obtain the most up-to-date information.

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

**Keep this leaflet with your medicine.**

You may want to read it again

#### What norfloxacin is used for

The name of your medicine is GenRx Norfloxacin. It contains the active ingredient, norfloxacin.

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. Norfloxacin may help stop 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.

Norfloxacin belongs to a group of antibiotics called quinolones (pronounced kwin - a - lones). Norfloxacin works by killing the bacteria causing the infection.

Your doctor may have prescribed norfloxacin for another reason.

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

#### Before you take it

*When you must not take it*

**Do not take norfloxacin if:**

- **you have an allergy to the active ingredient, norfloxacin, other quinolone antibiotics (for example ciprofloxacin or ofloxacin or any of the ingredients listed at the end of this leaflet.** Symptoms of an allergic reaction 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 breastfeeding.** Your baby may absorb this medicine in the womb or from breast milk and therefore there is a possibility of harm to the baby.
- **the packaging is torn or shows signs of tampering.**
- **the expiry date (EXP) on the pack has passed.** If you take this medicine after the expiry date has passed, it may not work.

**Do not give norfloxacin to children or to growing teenagers, unless advised by the doctor.**

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

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

*Before you start to take it*

**Tell your doctor if**

1. **You intend to become pregnant or intend to breast-feed.** Norfloxacin should not be used during pregnancy or while breast-feeding.
2. **You have any medical conditions, especially the following:**
  - kidney disease
  - seizures or fits or a history of them
  - Myasthenia gravis, a muscle disease.
3. **You have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.**

**If you have not told your doctor about any of the above, tell them before you take any norfloxacin.**

*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 and norfloxacin may interfere with each other. These include:

- nitrofurantoin, another antibiotic used to treat urinary tract infections
- theophylline and other methylxanthines, medicines used to treat asthma. Caffeine is also a methylxanthine.
- cyclosporin, a medicine commonly used in patients who have received organ transplants
- warfarin, phenindione and other medicines used to prevent blood clots
- probenecid, a medicine used to treat gout
- glibenclamide, a medicine used to treat diabetes
- non-steroidal anti-inflammatory medicines, used to treat muscular problems and arthritis. The combination of these medicines with norfloxacin may cause convulsions.
- erythromycin, another antibiotic used to treat and in some cases prevent infection
- cisapride, 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 heart beats such as sotalol, amiodarone, quinidine, and procainamide
- antipsychotics, a group of medicines used to treat certain mental & emotional conditions
- tricyclic antidepressants, a group of medicines 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 medicine, or you may need to take different medicines.

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

- iron or zinc supplements, and multivitamins containing them
- antacids used for indigestion
- sucralfate, a medicine 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.

Your doctor or pharmacist will tell you if you are taking any of these and they will have more information on other medicines to be careful with or avoid while taking norfloxacin.

#### How to take it

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

They may be different to the information in this leaflet.

If you do not understand any written instructions, 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 or not you are taking any other medicines.

The usual dose of norfloxacin 400mg tablets is one tablet twice a day.

*How to take it*

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

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

They may differ from the information contained in this leaflet.

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

*When to take it*

Take norfloxacin 400mg tablets 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 or after taking 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 of norfloxacin.

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

Taking norfloxacin at the same time or even within 2 hours of taking these can interfere with the absorption norfloxacin, so that the chance of norfloxacin fighting the infection won't be as good.

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

**Continue norfloxacin 400mg tablets until you finish the pack or until your doctor recommends.**

#### **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 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.**

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

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

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

#### *If you take too much (overdose)*

**Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice if you think that you or anyone else may have taken too much norfloxacin. Do this even if there are no signs of discomfort or poisoning. Keep telephone numbers of these places handy.**

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#### *While you are taking it*

##### *Things you must do*

**If you become pregnant while taking norfloxacin, tell your doctor immediately.**

**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.

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

Tell all the doctors, dentists and pharmacists who are treating you that you are taking norfloxacin.

#### *Things you must not do*

**Do not stop taking your tablets because you are feeling better, unless advised by your doctor.**

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.

**Do not give norfloxacin 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 norfloxacin 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, for example sleeplessness, anxiety, tremor, increased heartbeat and headache. Caffeine is contained in coffee, tea, cola drinks and some tablets.

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#### *Side effects*

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

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 treatment if you get some of the side effects.

Very rarely serious reactions involving the liver (hepatitis) have been reported. If you develop dark urine, pale stools, itching and/or yellowing of the skin or whites of the eyes (jaundice), during or after treatment with norfloxacin tell your doctor immediately.

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

#### *While taking norfloxacin*

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

- nausea
- headache
- dizziness, or light-headedness
- disturbances to vision.

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

- severe stomach pain
- symptoms of severe sunburn, such as redness, itching, pain, swelling or blistering
- pain, tenderness, swelling, or redness of muscles, joints or tendons
- bleeding or bruising more easily than normal, nose bleeds
- signs of anaemia, such as tiredness, being short of breath, and looking pale
- numbness or tingling in fingers or toes
- any signs of mental disturbance, such as confusion or hallucinations
- worsening of myasthenia gravis symptoms
- changes in hearing
- development of any pain, burning, tingling, numbness and/or weakness in arms or legs.

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

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

- 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
- 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.

These are all 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 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, this side effect is 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 any other effects.**

**Do not be alarmed by this list of possible side effects.**

You may not experience any of them.

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#### *After taking it*

##### *Storage*

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

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

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

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

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 the tablets, or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

### *Where to go for further information*

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

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## Product description

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### *What it looks like*

GenRx Norfloxacin 400 mg tablets are 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:**

Norfloxacin.

#### **Inactive ingredients:**

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

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*

Apotex Pty Ltd  
16 Giffnock Avenue  
Macquarie Park NSW 2113  
NSW 2113

GenRx is a registered trade mark of Apotex Pty Ltd.

Australian registration number:

AUST R 155546

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