

## Consumer Medicine Information

# ARROW - NORFLOXACIN

### *Norfloxacin 400 mg Tablets*

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## What is in this leaflet

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This leaflet answers some common questions about ARROW - NORFLOXACIN.

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 ARROW - NORFLOXACIN 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.

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## What ARROW - NORFLOXACIN is used for

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ARROW - NORFLOXACIN belongs to a group of antibiotics called quinolones. It is used to treat

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

ARROW - NORFLOXACIN is also used for patients who get frequent urinary tract infections. ARROW - 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 urinary 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.

ARROW - NORFLOXACIN works by killing the bacteria causing these infections.

**ARROW - NORFLOXACIN is not recommended to treat urinary tract infections in children or growing adolescents, as the safety of norfloxacin has not been adequately studied in this group of patients.**

Your doctor may have prescribed ARROW - NORFLOXACIN for another reason. Ask your doctor if you have any questions about why ARROW - NORFLOXACIN has been prescribed for you.

There is no evidence that ARROW - NORFLOXACIN is addictive.

ARROW - NORFLOXACIN is available only with a doctor's prescription.

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## **Before you take ARROW - NORFLOXACIN**

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### ***When you must not take it***

**Do not take ARROW - NORFLOXACIN if you are allergic to medicines containing norfloxacin, or 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
- lumpy skin rash ("hives"), hayfever or fainting
- muscle pain or tenderness, or joint pain.

**Do not take ARROW - NORFLOXACIN if 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.

**Do not take ARROW - NORFLOXACIN if the expiry date (Exp.) printed on the pack has passed.**

It may not work well if you do.

**Do not take ARROW - NORFLOXACIN if the packaging is torn or shows signs of tampering.**

### ***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 have or have had any medical conditions, especially the following:**

- kidney disease
- seizures or fits or a history of them
- myasthenia gravis, a muscle disease
- any heart rhythm problems.

**Tell your doctor if you are pregnant, intend to become pregnant or breastfeeding.**

**Tell your doctor if you are breastfeeding or intend to breastfeed.**

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

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

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

- nitrofurantoin, another antibiotic used to treat urinary tract infections
- erythromycin, an antibiotic used to treat and, in some cases, prevent infections
- theophylline, a medicine used to treat asthma
- cyclosporin, a medicine commonly used in patients who have received organ transplants
- warfarin, a medicine used to stop blood clots
- glibenclamide, a medicine used to treat diabetes
- probenecid, a medicine used to treat gout
- amiodarone, procainamide and sotalol, medicines used to treat irregular heart beats
- cisapride, a medicine used to treat gastric reflux
- antipsychotics, a group of medicines used to treat certain mental & emotional conditions
- tricyclic antidepressants, a group of medicines used to treat depression
- non-steroidal anti-inflammatory drugs.

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 ARROW - 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 ARROW - NORFLOXACIN. However, you must take ARROW - 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 and pharmacist have more information on medicines to be careful with or avoid while taking ARROW - NORFLOXACIN.

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

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## **How to take ARROW - NORFLOXACIN**

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**Follow all directions given to you by your doctor and pharmacist carefully.** These directions may differ from the information contained in this leaflet.

### ***How much to take ARROW - NORFLOXACIN***

The usual dose of ARROW - NORFLOXACIN is one tablet twice a day.

### ***How to take ARROW - NORFLOXACIN***

Take the tablet with a glass of water.

### ***When to take ARROW - NORFLOXACIN***

**Take your ARROW - NORFLOXACIN about twelve hours apart.**

Taking ARROW - 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 ARROW - NORFLOXACIN on an empty stomach, at least one hour before food or two hours after food.**

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 ARROW - NORFLOXACIN at the same time as taking iron or zinc supplements (or multivitamins containing them), antacids, sucralfate, or didanosine.**

Taking ARROW - NORFLOXACIN at the same time or even within two hours of taking these can interfere with the absorption of norfloxacin. This would affect the chance of ARROW - NORFLOXACIN fighting the infection.

### ***How long to take ARROW - NORFLOXACIN***

The length of your treatment will depend on the type of infection you have and how well you respond to the treatment. Continue taking ARROW - NORFLOXACIN until you finish the pack or until your doctor recommends.

**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 the tablets for up to 12 weeks.

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

Usually for five days.

***If you forget to take ARROW - NORFLOXACIN***

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.

***If you take too much ARROW - NORFLOXACIN (overdose)***

Immediately telephone your doctor, or the National Poisons Information Centre (0800 POISON or 0800 764 766), or go to the Accident and Emergency department at your nearest hospital, if you think that you or anyone else may have taken too many ARROW - NORFLOXACIN Tablets.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Keep the telephone numbers for these places handy.

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## **While you are taking ARROW - NORFLOXACIN**

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***Things you must do***

Before starting any new medicine, tell your doctor or pharmacist that you are taking ARROW - NORFLOXACIN.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking ARROW - NORFLOXACIN.

**Make sure to take your tablet every day and continue taking it until your doctor tells you to stop.**

This will ensure that all of the infection is gone and will lessen the chance of the infection coming back once you stop taking the tablets.

**If you develop severe diarrhoea, tell your doctor or pharmacist immediately. Do this even if it occurs several weeks after ARROW - 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 ARROW - 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 become pregnant while taking ARROW - NORFLOXACIN, tell your doctor immediately.**

**Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.**

Otherwise, your doctor may think that it is not working and change your treatment unnecessarily.

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

**Do not use ARROW - NORFLOXACIN to treat any other conditions unless your doctor tells you to.**

**Do not change the dose of your ARROW - NORFLOXACIN without checking with your doctor.**

**Do not give ARROW - NORFLOXACIN to anyone else, even if they have the same condition as you.**

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

**Be careful driving, operating machinery or doing jobs that require you to be alert while you are taking ARROW - NORFLOXACIN until you know how it affects you.**

ARROW - NORFLOXACIN can cause dizziness or light-headedness in some people. Make sure you know how you react to ARROW - 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, dizziness or light-headedness may be worse.

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

ARROW - 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 ARROW - NORFLOXACIN and tell your doctor.

**Be careful if you consume large amounts of caffeine while you are taking ARROW - NORFLOXACIN.**

ARROW - 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

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

Like other medicines, ARROW - NORFLOXACIN can cause some 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.

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

You may not experience any of them. 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
- headache
- dizziness.

These are the more common side effects of ARROW - NORFLOXACIN, and they are usually mild.

**Tell your doctor immediately 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
- pain, burning, tingling, numbness, and/or weakness in your arms or legs
- 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
- visual disturbances
- changes in your hearing
- decreased feeling or sensitivity, especially in the skin.

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

- watery and severe diarrhoea, which may also be bloody
- 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
- a rash together with very dry eyes and dry mouth
- severe and sudden onset of pinkish, itchy swellings on the skin, also called hives or nettle rash (not caused by sunburn)
- convulsion
- reduced urine output, pain, tenderness around kidney area.

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

### ***After finishing ARROW - NORFLOXACIN***

**Tell your doctor immediately if you notice any of the following problems, particularly if they occur several weeks after stopping treatment with ARROW - 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. ARROW - 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.

**Do not take any diarrhoea medicine without first checking with your doctor.** This is not a complete list of all possible side effects. 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.

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## **After taking ARROW - NORFLOXACIN**

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### ***Storage***

**Keep ARROW - NORFLOXACIN 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.

**Keep ARROW - NORFLOXACIN in a cool, dry place where the temperature stays below 30°C.**

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

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

**Do not store ARROW - NORFLOXACIN or other medicines in the bathroom or near a sink.**

**Do not leave the tablets in the car or on window sills.**

Heat, light and dampness can destroy some medicines.

### ***Disposal***

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

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## **Product description**

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### ***What it looks like***

ARROW - NORFLOXACIN is a white, film-coated, convex, oval-shaped scored tablet, embossed with "N|F" on one side and ">" on the other side.

ARROW - NORFLOXACIN is available in blister pack of 6 tablets, and in bottles of 6 and 100 tablets.

### ***Ingredients***

The active ingredient in ARROW - NORFLOXACIN is norfloxacin. Each ARROW - NORFLOXACIN Tablets contains 400 mg of norfloxacin.

The tablets also contain

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

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

### ***Supplier***

ARROW - NORFLOXACIN is distributed in New Zealand by:

Arrow Pharmaceuticals (NZ) Limited  
Mount Eden Central Business Park  
33a Normanby Road, Mt Eden  
Auckland, New Zealand.

### ***Date of preparation***

02<sup>nd</sup> June 2006