Norfloxacin Sandoz®
norfloxacin film-coated tablets
Consumer Medicine Information

What is in this leaflet
This leaflet answers some common questions about Norfloxacin Sandoz. 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.

WHAT NORFLOXACIN SANDOZ IS USED FOR
This medicine is used to treat:
• urinary tract infections
• infections of the stomach or intestines (such as traveller's diarrhoea).
This medicine is also used to prevent urinary tract infections in people who get them frequently.
It contains the active ingredient norfloxacin.
Norfloxacin belongs to a group of medicines called quinolone antibiotics.
It works by killing the bacteria causing the infection.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.
Your doctor may have prescribed it for another reason.
This medicine is not addictive.
This medicine is available only with a doctor's prescription.

Before you take Norfloxacin Sandoz
When you must not take it
Do not take this medicine if you have an allergy to:
• norfloxacin, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product Description
• any other similar medicines, such as other quinolone antibiotics (e.g. ciprofloxacin).
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
• muscle pain or tenderness
• joint pain.
Do not take this medicine if you are pregnant.
It may affect your developing baby if you take it during pregnancy.
Do not breastfeed if you are taking this medicine.

The active ingredient in Norfloxacin Sandoz may pass into breast milk and there is a possibility that your baby may be affected.

Do not give this medicine to children or growing adolescents, unless advised by the doctor.

Safety in children and growing adolescents has not been established.

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 problems
• seizures or fits
• myasthenia gravis (a condition where your muscles become weak and tire easily)
• heart problems
• glucose-6-phosphate dehydrogenase deficiency.
If you have not told your doctor about any of the above, tell him/her before you start taking Norfloxacin Sandoz.
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 Sandoz may interfere with each other. These include:

- some antibiotics such as nitrofurantoin and erythromycin
- theophylline, a medicine used to treat asthma
- probenecid, a medicine used to treat gout
- certain medicines that are processed by a specific liver enzyme, such as tacrine or tizanidine
- glibenclamide, a medicine used to treat diabetes
- cisapride, a medicine used to treat heartburn
- sucralfate, a medicine used to treat duodenal or stomach ulcers
- some medicines used in organ transplantation, such as cyclosporin and mycophenolic acid
- NSAIDs (non-steroidal anti-inflammatory drugs), medicines used to treat pain, swelling and arthritis
- ropinirole, a medicine used to treat Parkinson's disease and restless legs syndrome
- multivitamins, mineral supplements and other medicines containing iron, zinc, magnesium, aluminium or calcium
- tricyclic antidepressants, a group of medicines used to treat depression, such as amitriptyline and nortriptyline
- clozapine, a medicine used to treat schizophrenia
- antipsychotics, medicines used to treat certain mental and emotional conditions

- some medicines used to treat irregular heart beats such as sotalol, amiodarone, quinidine and procainamide
- didanosine (Videx), an antiviral medicine used to treat HIV infection
- anticoagulants, medicines used to prevent blood clots, such as warfarin and phenindione.

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

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

How to take NORFLOXACIN SANDOZ

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, ask your doctor or pharmacist for help.

How much to take

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, Norfloxacin Sandoz may not work as well and your problem may not improve.

The usual dose is one tablet twice a day.

How to it

Swallow the tablets whole with a full glass of water.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

Take your medicine on an empty stomach, for example, 1 hour before food or 2 hours after food.

Food can interfere with the absorption of this medicine.

If you need to take an antacid, multivitamins, supplements containing iron, calcium or zinc, didanosine (Videx) or sucralfate, take it at least 2 hours before or 2 hours after your dose of Norfloxacin Sandoz.

How long to take it

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

If you forget to take it

Take your dose as soon as you remember, and continue to take it as you would normally.

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

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

**WHILE YOU ARE TAKING NORFLOXACIN SANDOZ**

**Things you must do**

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

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

If you become pregnant while taking this medicine, tell your doctor immediately.

If you develop severe diarrhoea, tell your doctor or pharmacist immediately. Do this even if it occurs several months after Norfloxacin Sandoz 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 (e.g. Lomotil) without first checking with your doctor.

Drink plenty of water or fluids while taking Norfloxacin Sandoz.

This will help to prevent crystals forming in the urine which can cause kidney problems.

**Things you must not do**

Do not take Norfloxacin Sandoz 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.

If you do not complete the full course prescribed by your doctor, your infection may not clear completely, or it may return.

**Things to be careful of**

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

This medicine may cause tiredness, dizziness or light-headedness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while you are taking this medicine.

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

Avoid excessive exposure to direct sunlight.

Your skin may become more prone to sunburn.

Be careful if you consume large amounts of caffeine while you are taking Norfloxacin Sandoz.

This medicine may increase the stimulatory effects of caffeine.

**SIDE EFFECTS**

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

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.

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:

- headache
- dizziness or light-headedness
- feeling sick (nausea) or vomiting
- tiredness
- mild stomach upsets such as stomach discomfort, constipation, diarrhoea or flatulence
- heartburn
- dry mouth or changes in taste
- disturbances to vision
- discharge, itching or irritation in the vagina
- difficulty sleeping.

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
- signs of anaemia, such as tiredness, being short of breath and looking pale
- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- numbness or tingling in fingers or toes
- irritability, agitation, confusion, depression or hallucinations
- worsening of myasthenia gravis symptoms
- any changes in your hearing
- changes in heart rate (faster, slower or irregular)
- development of any pain, burning, tingling, numbness and/or weakness in your arms or legs.

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:

- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- wheezing or shortness of breath
- severe and sudden onset of pinkish, itchy swellings on the skin (e.g. hives) not caused by sunburn
- severe, watery diarrhoea, which may be bloody
- yellowing of the skin and/or eyes (jaundice)
- sudden and severe pain or swelling of muscles, joints or tendons
- convulsions
- passing little or no urine, blood in the urine, pain or tenderness around the kidney areas.

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

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

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

Some of side effects, such as liver, blood or kidney problems can only be found when your doctor does tests from time to time to check your progress.

Keep your medicine in a cool dry place where the temperature stays below 25°C.

Do not store Norfloxacin Sandoz 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.

PRODUCT DESCRIPTION

What it looks like

Norfloxacin Sandoz comes in one strength:

Norfloxacin Sandoz 400mg - white, biconvex, oval, film-coated tablets.

Available in blisters of 14 tablets.

Ingredients

Active ingredients:

- Norfloxacin Sandoz 400mg - 400mg norfloxacin.

Inactive ingredients:

- microcrystalline cellulose
- croscarmellose sodium
- colloidal anhydrous silica
- magnesium stearate
- purified talc
- hypromellose
- macrogol 4000
- titanium dioxide
- propylene glycol
- lactose.

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Norfloxacin Sandoz is supplied in Australia by:
Sandoz Pty Ltd
ABN 60 075 449 553
Level 2, 19 Harris Street
Pyrmon NSW 2009
Australia
Tel: 1800 634 500

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