

APO-NORFLOXACIN

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

WARNING: Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

1. Why am I using APO-NORFLOXACIN?

APO-NORFLOXACIN contains the active ingredient norfloxacin. APO-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.

For more information, see Section [1. Why am I using APO-NORFLOXACIN?](#) in the full CMI.

2. What should I know before I use APO-NORFLOXACIN?

Do not use if you have ever had an allergic reaction to APO-NORFLOXACIN or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use APO-NORFLOXACIN?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with APO-NORFLOXACIN and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use APO-NORFLOXACIN?

- The usual dose for APO-NORFLOXACIN tablets is one tablet twice a day.
- Your doctor will determine the duration of time that you take the tablets depending on your condition and whether you are taking any other medicines.

More instructions can be found in Section [4. How do I use APO-NORFLOXACIN?](#) in the full CMI.

5. What should I know while using APO-NORFLOXACIN?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using APO-NORFLOXACIN.• If you develop severe diarrhoea, tell your doctor or pharmacist immediately. Do this even if it occurs several weeks after APO-NORFLOXACIN has been stopped.• Tell your doctor immediately if you become pregnant or start to breastfeed while taking this medicine.• If you are about to start taking a new medicine, tell your doctor and pharmacist that you are taking APO-NORFLOXACIN.
Things you should not do	<ul style="list-style-type: none">• Do not give APO-NORFLOXACIN to anyone else, even if they have the same condition as you.• Do not take APO-NORFLOXACIN to treat any other complaints unless your doctor tells you to.• Do not stop taking APO-NORFLOXACIN or change the dosage without checking with your doctor.• Do not take APO-NORFLOXACIN after the expiry date printed on the pack.
Driving or using machines	<ul style="list-style-type: none">• APO-NORFLOXACIN tablets may cause dizziness or light-headedness in some people.• Be careful before you drive or use any machines until you know how APO-NORFLOXACIN affects you.
Looking after your medicine	<ul style="list-style-type: none">• Store it in a cool dry place away from moisture, heat or sunlight, where the temperature stays below 30°C.• Keep your tablets in the blister pack until it is time to take them. If you take the tablets out of the box or the blister pack they may not keep well.

For more information, see Section [5. What should I know while using APO-NORFLOXACIN?](#) in the full CMI.

6. Are there any side effects?

Less serious side effects may include rash, headache, dizziness, tiredness, nausea, vomiting, stomach pain, vaginal thrush. **Serious side effects** may include fainting, seizures, depression, diarrhoea, tendon pain, swelling or rupture, pain, burning, numbness or tingling in the fingers or toes, eyesight problems, changes in mood or thoughts, skin reactions, blistering or peeling, and yellowing of the skin or eyes. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

WARNING:**Serious disabling and potentially irreversible adverse reactions**

Fluoroquinolones, including norfloxacin, have been associated with serious side effects, some of them being long lasting, disabling or potentially irreversible.

These include but are not limited to serious side effects involving musculoskeletal system disorders such as pain and swelling in the joints and inflammation or rupture of tendons, nervous system disorders such as nerve damage (neuropathy) resulting in pain, burning, tingling, numbness and/or weakness especially in the feet and legs or hands and arms, psychiatric disorders such as anxiety, confusion, depression or self-harming behaviour.

These serious side effects may occur in patients of any age or without pre-existing factors.

APO-NORFLOXACIN

Active ingredient: *norfloxacin*

Consumer Medicine Information (CMI)

This leaflet provides important information about using APO-NORFLOXACIN. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using APO-NORFLOXACIN.**

Where to find information in this leaflet:

- [1. Why am I using APO-NORFLOXACIN?](#)
- [2. What should I know before I use APO-NORFLOXACIN?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use APO-NORFLOXACIN?](#)
- [5. What should I know while using APO-NORFLOXACIN?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using APO-NORFLOXACIN?

APO-NORFLOXACIN contains the active norfloxacin. APO-NORFLOXACIN belongs to a group of antibiotics called quinolones. It works by killing the bacteria causing the infection.

APO-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.

2. What should I know before I use APO-NORFLOXACIN?

Warnings

Do not use APO-NORFLOXACIN if:

- you are allergic to norfloxacin, or any of the ingredients listed at the end of this leaflet.
 - 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
- Always check the ingredients to make sure you can use this medicine.
- other quinolone antibiotics (for example ciprofloxacin or ofloxacin).
- You are pregnant or intend to become pregnant, or are breastfeeding – see 'Pregnancy and Breastfeeding' section below.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

APO-NORFLOXACIN is not recommended if you are pregnant

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Children under 18 years old

APO-NORFLOXACIN should not be used in children under 18 years of age.

3. What if I am taking other medicines?

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

Some medicines may interfere with APO-NORFLOXACIN and affect how it works. 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.

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. During treatment with

norfloxacin, the ingestion of caffeine containing medications (eg certain analgesics) should be avoided where possible.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect APO-NORFLOXACIN.

4. How do I use APO-NORFLOXACIN?

How much to take / use

- The usual dose is one tablet twice a day.
- Follow the instructions provided when APO-NORFLOXACIN was prescribed, including the number of days it should be taken.

When to take / use APO-NORFLOXACIN

- **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 to take APO-NORFLOXACIN

Swallow the tablets with a full glass of water.

How long to take APO-NORFLOXACIN

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

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 use APO-NORFLOXACIN

APO-NORFLOXACIN should be used regularly at the same time each day.

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 you missed.

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

If you use too much APO-NORFLOXACIN

If you think that you have used too much APO-NORFLOXACIN, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using APO-NORFLOXACIN?

Things you should do

- tell all doctors, dentists and pharmacists who are treating you that you are taking APO-NORFLOXACIN.
- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking APO-NORFLOXACIN tablets.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.
- 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
- **protect your skin when you are in the sun, especially between 10 am and 3 pm.** APO-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.** APO-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.

Call your doctor straight away if you:

- become pregnant or start to breastfeed while taking APO-NORFLOXACIN

- develop an allergic reaction (e.g. skin rash) while taking APO-NORFLOXACIN, even following a single dose. Stop taking it and tell your doctor
- **develop severe diarrhoea.** Tell your doctor even if it occurs several weeks after you have stopped taking APO-NORFLOXACIN.
- feel any discomfort, pain, swelling or inflammation of a tendon.
- experience symptoms of depression or self-harming behaviour. APO-NORFLOXACIN should be discontinued.
- develop pain, burning, tingling, numbness or weakness in any part of the body. APO-NORFLOXACIN should be discontinued immediately.

Remind any doctor, dentist or pharmacist you visit that you are using APO-NORFLOXACIN.

Things you should not do

- Do not use APO-NORFLOXACIN to treat any other complaints unless your doctor tells you to.
- Do not give your APO-NORFLOXACIN to anyone else, even if they have the same condition as you.
- **Do not stop taking your tablets or lower the dosage without checking with your doctor.**

Driving or using machines

Be careful before you drive or use any machines or tools until you know how APO-NORFLOXACIN affects you.

APO-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.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

Keep your tablets in the blister pack until it is time to take them. If you take the tablets out of the box or the blister pack, they may not keep well.

Store it in a cool dry place away from moisture, heat or sunlight where the temperature stays below 30°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> nausea, upset stomach, stomach pain headache dizziness disturbances to vision rash tiredness, changes in sleep pattern vaginal thrush - sore and itchy vagina or discharge 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> increased sensitivity of the skin to the sun, with symptoms of sunburn (redness, blistering or itching) happening more quickly than usual confusion, depression, hallucinations changes in mood, disorientation, increased irritability, increased anxiety or nervousness 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 abnormally fast heart rate worsening of the symptoms of myasthenia gravis decreased feeling or sensitivity, especially in the skin changes in your hearing. 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> severe abdominal cramps or stomach cramps watery and severe diarrhoea, which may also be bloody pain, tenderness, swelling, or redness of muscles, joints or tendons pain, burning, tingling, numbness, and/or weakness in your arms or legs skin rash, together with dry eyes and dry mouth severe and sudden onset of pinkish, itching or hives or peeling or blistering of the skin (not caused by sunburn) 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 	<p>passing little or no urine, blood in the urine, tenderness around kidney area.</p> <p>Tell your doctor immediately if you notice any of the following, even if they occur several weeks after stopping treatment with norfloxacin:</p> <ul style="list-style-type: none"> 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

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

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at

www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What APO-NORFLOXACIN contains

Active ingredient (main ingredient)	Norfloxacin
Other ingredients (inactive ingredients)	microcrystalline cellulose croscarmellose sodium magnesium stearate Opadry AMB OY-B-28920.
Potential allergens	Contains soya beans.

Do not take this medicine if you are allergic to any of these ingredients.

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

What APO-NORFLOXACIN 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.

Who distributes APO-NORFLOXACIN

Arrotex Pharmaceuticals Pty Ltd

15 – 17 Chapel Street

Cremorne VIC 3121

www.arrotex.com.au

This leaflet was prepared in March 2026.