

Nufloxib

norfloxacin

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Nufloxib. 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 Nufloxib 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 your medicine.

You may need to read it again.

What Nufloxib is used for

The name of your medicine is Nufloxib. It contains the active ingredient norfloxacin.

Nufloxib is an antibiotic that belongs to a group of medicines called quinolones. Nufloxib works by killing the bacteria that are causing your infection in different parts of the body.

Nufloxib is also used to treat;

- Treat urinary tract infections
- Treat gastrointestinal infections, in particular shigellosis and traveller's diarrhoea.

Nufloxib will not work against infections caused by viruses, such as colds or the flu.

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

Your doctor may have prescribed Nufloxib for another reason.

Nufloxib is not addictive.

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

Before you take Nufloxib

When you must not take Nufloxib

Do not take Nufloxib if you have an allergy to

- other products containing norfloxacin (such as Noroxin, Norflohexal, Insensye)
- any other quinolone antibiotic such as Avelox, C-Flox

- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include asthma, wheezing, shortness of breath, swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing. Symptoms may also include skin rash, itching, hives or joint pain.

Do not give Nufloxib to children or to growing teenagers (under the age of 18), unless advised by the doctor.

The safety and effectiveness of Nufloxib in children have not been established.

Do not take this medicine if you are pregnant, or intend to become pregnant.

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

Do not take this medicine if you are breastfeeding or intend to breastfeed.

The active ingredient in Nufloxib may pass into breast milk and may affect your baby.

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 Nufloxib, talk to your doctor.

Before you start to take Nufloxib

Tell your doctor if you have any allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes

Tell your doctor if you intend to become pregnant or intend to breastfeed.

Nufloxib should not be used during pregnancy or while breast-feeding.

Tell your doctor if you have or have had any other health problems or medical conditions, including:

- kidney disease
- seizures or fits or a history of them
- myasthenia gravis, a condition that affects the muscles
- glucose-6-phosphate dehydrogenase deficiency
- heart rhythm problems.
- Arthropathy
- Crystalluria

- Vision disorders
- Tendon inflammation

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

Taking other medicines

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

Some medicines may interfere with Nufloxib. These include:

- theophylline (such as Nuelin), a medicine used to treat asthma
- warfarin (such as Coumadin, Marevan), a medicine used to prevent blood clots
- phenindione (such as Dindevan), a medicine also used to prevent blood clots
- probenecid (Pro-Cid), a medicine used to treat gout
- nitrofurantoin (Ralodantin, Macrochantin), a medicine used to treat urinary tract infections
- ciclosporin (Neoral, Sandimmun, Cysporin), a medicine used to suppress the immune system

- certain drugs that are metabolised by a specific enzyme: clozapine, ropinirole, tacrine, tizanidine
- glibenclamide, a medicine used to treat diabetes
- metronidazole (such as Flagyl, Metrogyl), a medicine used to treat various types of bacterial infections
- non-steroidal anti-inflammatory drugs (NSAIDs), medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis
- erythromycin, a medicine used to treat infections
- cisapride, a medicine used to treat gastric reflux, usually experienced as heartburn
- some medicines used to treat irregular heart beats such as sotalol, amiodarone, quinidine and procainamide
- antipsychotics, medicines used to treat certain mental and emotional conditions
- tricyclic antidepressants, medicines used to treat depression such as amitriptyline and nortriptyline.

These medicines may be affected by Nufloxib, 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 Nufloxib. These include:

- iron or zinc supplements, and multivitamins containing them
- calcium preparations
- antacids (such as Mylanta, Alu-Tab, Gastrogel) used for indigestion
- sucralfate (Ulcyte, Carafate), a medicine used to treat stomach ulcers
- didanosine (Videx and Videx EC), a medicine used to treat HIV infections.

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

Nufloxib may prolong the effect of coffee and other drinks containing caffeine.

Your doctor or pharmacist will be able to tell you what to do when taking Nufloxib with other medicines.

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

How to take Nufloxib

Follow all directions given to you by your doctor carefully.

These directions may differ from the information contained in this leaflet.

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

How much to take

Your doctor will tell you how many tablets you will need to take each day. This depends on your condition (for example if you have a kidney problem) and whether you are taking any other medicines.

The usual dose of Nufloxib is one 400 mg tablet morning and evening on an empty stomach.

The maximum total daily dose of Nufloxib should not exceed 800 mg per day.

How to take it

Swallow Nufloxib with a glass of water.

When to take it

Take Nufloxib on an empty stomach. For example, one hour before food or two hours after food.

This will give the tablets a better chance of fighting the infection because food can interfere with the absorption of Nufloxib.

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

Taking Nufloxib at the same time or even within two hours of taking these can interfere with the absorption of Nufloxib, so

that the chance of Nufloxib fighting the infection won't be as good.

How long to take it

Continue taking Nufloxib until you finish the pack or until your doctor tells you to.

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

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

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

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) or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much Nufloxib. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using Nufloxib

Things you must do

If you become pregnant while you are taking Nufloxib tell your doctor immediately.

If you get severe diarrhoea, tell your doctor or pharmacist immediately. Do this even if it occurs several weeks after Nufloxib 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 Nufloxib.

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

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

Nufloxib may cause your skin to be much more sensitive to sunlight than it is normally. This may cause a skin rash, itching, redness, or a severe sunburn.

If outdoors, wear protective clothing and use a 30+ sunscreen. If your skin does appear to be burning, stop taking Nufloxib and tell your doctor.

If the symptoms of your infection do not improve within a few days, or if they become worse, tell your doctor.

If you are about to start taking any new medicine, tell your doctor and pharmacist that you are taking Nufloxib.

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

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, all 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 Nufloxib to anyone else, even if they have the same condition as you.

Do not use Nufloxib to treat any other complaints unless your doctor tells you to.

Things to be careful of

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

Nufloxib may cause dizziness or light-headedness in some people. Make sure you know how you react to Nufloxib 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.

Side effects

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

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.

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

While you are using Nufloxib

Tell your doctor 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 immediately 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.

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

If any of the following happen, stop taking Nufloxib and 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.

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

After finishing Nufloxib

Tell your doctor immediately if you notice any of the following side effects, particularly if they occur several weeks after stopping treatment with Nufloxib:

- 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. You may have a serious condition affecting your bowel. You may need urgent medical attention. However, these side effects are 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 anything that is making you feel unwell.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using Nufloxib

Storage

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

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

Keep Nufloxib in a cool dry place where the temperature stays below 25°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 a window sill.

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 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 tablets that are left over.

Product description

What it looks like

Nufloxib are white, oval, biconvex, film-coated tablets.

Each pack contains 14 tablets.

Ingredients

Active:

Each Nufloxib tablet contains 400 mg of the active ingredient norfloxacin.

Inactive ingredients:

Each Nufloxib tablet also contains:

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

Nufloxib does not contain gluten, sucrose, tartrazine or any other azo dyes. Nufloxib contains lactose.

Supplier

Nufloxib is supplied in Australia by:

Alphapharm Pty Limited

Level 1, 30 The Bond

30 - 34 Hickson Road

Millers Point NSW 2000

www.mylan.com.au

Registration number:

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