

Noumed Ciprofloxacin

ciprofloxacin hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Noumed Ciprofloxacin.

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 risks and benefits. Your doctor has weighed the risks of you taking Noumed Ciprofloxacin against the benefits it is expected to 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 this medicine is used for

Noumed Ciprofloxacin is used to treat certain bacterial infections such as:

- kidney and bladder infections
- bowel infections
- lung infections
- skin infections
- bone and joint infections
- prostate infections.

Noumed Ciprofloxacin tablets contain the active ingredient, ciprofloxacin, which is an antibiotic belonging to a group of medicines called quinolones (pronounced KWIN-a-lones).

This medicine works by killing the bacteria which cause these

infections. This helps your body to fight the infection.

This medicine will not work against viral infections such as colds or flu.

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

Your doctor may have prescribed it for another reason.

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

There is no evidence that Noumed Ciprofloxacin is addictive.

This medicine is not recommended for use in children or growing teenagers.

Before you take this medicine

When you must not take it

Do not take Noumed Ciprofloxacin if you have an allergy to:

- ciprofloxacin, the active ingredient in Noumed Ciprofloxacin
- any of the ingredients listed at the end of this leaflet
- any other medicines belonging to the quinolone chemical family such as moxifloxacin, norfloxacin, or nalidixic acid.

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.

Do not take Noumed

Ciprofloxacin if you are also taking a medicine called tizanidine, a muscle relaxant used to treat spasticity associated with multiple sclerosis, injury or diseases of the spinal cord.

Noumed Ciprofloxacin can interfere with tizanidine and can lead to undesirable side effects such as low blood pressure and drowsiness.

Do not take this medicine after the expiry date (EXP) 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, including aspirin or non-steroidal anti-inflammatory drugs (NSAIDs), or any other substances such as foods, preservatives or dyes.

Tell your doctor if you are pregnant or plan to become pregnant.

Noumed Ciprofloxacin is not recommended if you are pregnant but your doctor will assess the benefit if required. Medicines similar to Noumed Ciprofloxacin have caused joint disease in immature animals.

Tell your doctor if you are breastfeeding.

Noumed Ciprofloxacin is excreted into the breast milk. Your doctor will tell you whether you should take it and temporarily stop

breastfeeding while you are taking the tablets.

Noumed Ciprofloxacin should be used with caution in elderly patients as they are more prone to side effects.

Tell your doctor if you:

- suffer from epilepsy (seizures, convulsions), have had a stroke, or have kidney or liver disease
- have arrhythmias (fast or irregular heartbeats). Noumed Ciprofloxacin may increase the risk of arrhythmias, especially in the elderly or patients with low potassium levels
- have previously taken corticosteroids. You may be at increased risk of swelling of the tendons. Symptoms include pain, tenderness and sometimes restricted movement
- have myasthenia gravis, a condition where the muscles become weak. Noumed Ciprofloxacin can worsen the symptoms of this condition
- have a history of tendon disorders with the use of quinolones (e.g. moxifloxacin, norfloxacin, nalidixic acid)
- have or have had mental illness
- have diabetes

If you have not told your doctor about any of the above, tell them before you start taking Noumed Ciprofloxacin.

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 Noumed Ciprofloxacin may interfere with each other. These include:

- tizanidine, a muscle relaxant used to treat spasticity associated with multiple sclerosis, injury or diseases of the spinal cord

- medicines used to treat arrhythmias (fast or irregular heartbeats)
- theophylline, a medicine to control asthma
- oral anticoagulants, warfarin and its metabolites, medicines used to stop blood clots
- phenytoin, a medicine used to treat epilepsy
- oral antidiabetic agents
- didanosine, a medicine used to treat viral infections
- cyclosporin, a medicine used to control the body's immune system
- non-steroidal anti-inflammatory drugs (NSAIDs), medicines used to treat pain, arthritis and other inflammatory conditions
- methotrexate, a medicine used to treat certain types of cancers, severe psoriasis or severe rheumatoid arthritis
- duloxetine, a medicine used to treat depression, anxiety, and nerve pain in people with diabetes
- clozapine, a medicine used to treat schizophrenia
- ropinirole, a medicine used to treat Parkinson's disease or restless legs syndrome
- the local anaesthetic lidocaine, a medicine used to numb pain or cause loss of sensation
- oxpentifylline, a medicine used to treat circulation disorders
- sildenafil, a medicine used to treat erectile dysfunction
- agomelatine, a medicine used to treat depression
- zolpidem, a medicine used to treat sleep disorders.

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

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

- multivitamins, mineral supplements, antacids (used for indigestion) and other medicines containing iron, zinc, magnesium, aluminium or calcium
- sucralfate, a medicine used to treat duodenal or stomach ulcers
- medicines used to treat HIV infection
- probenecid, a medicine used to treat gout
- omeprazole, a medicine used to treat stomach ulcers and other conditions where stomach produces too much acid
- sevelamer, a medicine used to treat high blood levels of phosphorus in patients with kidney disease who are on dialysis
- metoclopramide, a medicine used to relieve nausea and vomiting, heartburn, and stomach pain

You can still take these medicines while you are taking Noumed Ciprofloxacin.

However, you must take Noumed Ciprofloxacin at least 2 hours before or 2 hours after taking any of these medicines to make sure it is absorbed properly.

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

How to take this medicine

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 on the box/bottle, ask your doctor or pharmacist for help.

How much to take

Your doctor or pharmacist will tell you how much and how often you should take Noumed Ciprofloxacin. This will depend on the type of infection and any medical conditions you may have.

The usual adult dosage for most infections is one tablet twice daily for 7 to 14 days. You may need to take your tablets for a longer period for some type of infections. The dose will be determined by your doctor as it depends on the type of infection you have.

How to take it

Swallow the tablets whole with a full glass of water.

Avoid taking this medication at the same time as milk, yoghurt or other products that are high in calcium. These products will interfere with the absorption of Noumed Ciprofloxacin from the stomach.

However, if the milk, yoghurt or other high calcium products are ingredients of a meal, they will not interfere with Noumed Ciprofloxacin absorption.

When to take it

Noumed Ciprofloxacin tablets are usually taken twice a day.

Take your tablets at 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.

It does not matter if you take this medicine before or after food.

If you need to take an antacid, take it at least 2 hours before or 2 hours after your dose of Noumed Ciprofloxacin.

How long to take it

The length of treatment may vary from 1 to 28 days or longer depending on the type of infection.

Continue taking Noumed Ciprofloxacin until you finish the

pack or for as long as your doctor tells you.

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.

Check with your doctor if you are not sure how long you should be taking it for.

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 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 Australia 13 11 26 or New Zealand 0800 POISON or 0800 764 766) 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 Noumed Ciprofloxacin.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking this medicine

Things you must do

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

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

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

Noumed Ciprofloxacin may affect the results of certain laboratory tests.

If you are about to have any tests, tell your doctor that you are taking this medicine.

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

Drink plenty of water or fluids while taking this medicine.

This will help to prevent crystals forming in the urine which can cause kidney problems. However, this is not a common problem.

Protect your skin when you are in the sun, especially between 10 am and 3 pm, or in the presence of artificial ultraviolet (UV) light.

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

If outdoors, wear protective clothing and use a 15+ sunscreen.

If your skin does appear to be burning, stop taking this medicine and tell your doctor.

If you get severe diarrhoea tell your doctor or pharmacist immediately. Do this even if it occurs several weeks after Noumed Ciprofloxacin 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 anti-diarrhoea medicine without first checking with your doctor.

If you get a sore white mouth or tongue while taking or soon after stopping Noumed Ciprofloxacin, tell your doctor. Also tell your doctor if you get vaginal itching or discharge.

This may mean you have a fungal infection called thrush. Sometimes the use of this medicine allows fungi to grow and the above symptoms to occur. Noumed Ciprofloxacin does not work against fungi.

Tell your doctor immediately if you experience symptoms of depression or self-endangering behaviour.

Noumed Ciprofloxacin should be discontinued immediately.

Tell your doctor immediately if you develop pain, burning, tingling, numbness or weakness in any part of the body.

Noumed Ciprofloxacin should be discontinued immediately.

Things you must not do

Do not use Noumed Ciprofloxacin 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 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 and be more difficult to treat.

Things to be careful of

Avoid excessive exposure to direct sun.

Your skin may become more prone to sunburn. If such a reaction

occurs, stop taking Noumed Ciprofloxacin immediately and tell your doctor.

Be careful driving or operating machinery, until you know how Noumed Ciprofloxacin affects you.

This medicine may cause dizziness, light-headedness or drowsiness in some people. If you have any of these symptoms, do not drive or 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, dizziness, light-headedness or drowsiness may be worse.

Be careful when drinking beverages containing caffeine (e.g. coffee, cola drinks) while you are taking this medicine.

Noumed Ciprofloxacin tablets 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 Noumed Ciprofloxacin.

This medicine helps most people with bacterial infections, 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.

If you are over 65 years of age you may have an increased chance of getting side effects.

Do not be alarmed by the following list 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:

- nausea or vomiting
- mild diarrhoea

The above list includes more common side effects of Noumed Ciprofloxacin. They are usually mild and short-lived.

If any of the following happens, tell your doctor immediately, or go to Accident and Emergency at the nearest hospital:

- severe skin rashes, peeling of the skin and/or mucosal reactions
- signs of allergy such as rash, swelling of the face, lips, mouth, throat or other parts of the body, shortness of breath, wheezing or trouble breathing
- fainting
- yellowing of the skin and eyes, also called jaundice
- severe watery or bloody diarrhoea, even if it occurs several weeks after taking your tablets
- fits (seizures, convulsions)
- confusion, nightmares, hallucinations and psychotic reaction (even progressing to self-endangering behaviour)
- fast or irregular heartbeats
- visual disturbances
- ringing in the ear, loss of hearing
- abdominal pain/cramps. Very rarely this can progress to a serious condition accompanied by fever and fatigue.
- pain, burning, tingling, numbness and/or weakness in your limbs.
- hypersensitivity reaction called DRESS (Drug reaction with Eosinophilia and Systemic Symptoms) which may include fever, extensive skin rash, swollen lymph nodes, blood abnormalities and inflammation of internal organs like liver, lung, or kidney.

These serious side effects are rare. If you have them, you may need urgent medical attention

In isolated instances, some serious side effects may be long lasting (>30 days) and disabling, such as tendonitis, tendon rupture, musculoskeletal disorders and other reactions affecting the nervous system including mental health disorders and disturbances of senses.

Photosensitivity (getting sunburnt very easily) can occur occasionally with ciprofloxacin. However, it is temporary and staying out of direct sunlight while on ciprofloxacin will prevent it from happening.

Rarely, there are worsening of the symptoms of myasthenia gravis. This is a condition in which the muscles become weak and tire easily, causing drooping eyelids, double vision, difficulty speaking and swallowing and sometimes muscle weakness in the arms and legs.

Rarely, the Achilles tendon (extending from the calf to the heel of the foot) or other tendons have been torn after ciprofloxacin therapy. This may occur even within the first 48 hours of treatment. This risk of tendon damage may be increased in elderly patients during strenuous physical activity, if currently being treated with a type of medicine called corticosteroids, if you have reduced kidney function or have received solid organ transplants. Tell your doctor immediately if you feel any discomfort, pain, or inflammation of a tendon.

Rarely, you may experience hyperglycaemia (high blood sugar), or hypoglycaemia (low blood sugar). Symptoms of hyperglycaemia include increased thirst, appetite, and urination. Symptoms of hypoglycaemia include weakness, shaking, sweating, light-headedness, headache, behavioural changes,

confusion, numbness/ pins and needles in the lips, fingers or toes, irritability, and hunger.

If you experience any of these symptoms during treatment, tell your doctor or pharmacist immediately. Noumed Ciprofloxacin may need to be discontinued.

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

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

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

You may not experience any of them.

After finishing it

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

- 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.

Do not take any anti-diarrhoea medicine without first checking with your doctor.

You may have a serious condition affecting your bowel, and may therefore need urgent medical attention. However, this side effect is rare.

After taking this medicine

Storage

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

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

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

Do not store Noumed Ciprofloxacin 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

Noumed Ciprofloxacin tablets are available in two strengths, each in blister packs of 14 tablets:

- 500 mg – white to off-white, caplet (oval)-shaped, film-coated tablets marked with “500” on one side and plain on the other.
- 750 mg – white to off-white, caplet (oval)-shaped, film-coated tablets marked with “750” on one side and plain on the other.

Ingredients

Active ingredient:

Noumed Ciprofloxacin tablets contain 500 mg or 750 mg of the active ingredient, ciprofloxacin (as hydrochloride).

Inactive ingredients:

Noumed Ciprofloxacin also contains:

- microcrystalline cellulose
- maize starch
- magnesium stearate
- purified talc
- anhydrous colloidal silica

- sodium starch glycollate
- purified water
- hypromellose
- titanium dioxide
- macrogol 400.

Australian Register Numbers

Noumed Ciprofloxacin 500 mg tablets – AUST 324493.

Noumed Ciprofloxacin 750 mg tablets – AUST R 324494.

Sponsor

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