

ENOXIN TABLET®

Ciprofloxacin (500mg)

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What Enoxin is used for

Enoxin contains ciprofloxacin as active substance. It is a fluoroquinolone antibacterial agent. It can be used to treat or prevent infections caused by bacteria which include infections of respiratory tract, eyes, ears, urinary tract, genital organs, gastrointestinal tract, skin, bones and joints, sepsis, infection in individuals with reduced immunity.

How Enoxin works

Ciprofloxacin kills bacteria that cause infections by inhibiting the reproduction of essential enzyme for bacterial DNA. It only works with specific strains of bacteria.

Before you use Enoxin

- When you must not take it

- allergic (hypersensitive) to the active substance, to other quinolone drugs or to any of the other ingredients of Enoxin
- if you are pregnant, trying to get pregnant or think you may be pregnant
- if you are breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start use it

Tell your doctor if you:

- have ever had kidney problems because your treatment may need to be adjusted
- suffer from epilepsy or other neurological conditions
- have a history of tendon problems during previous treatment with antibiotics such as Enoxin

- have myasthenia gravis (a type of muscle weakness)
- have a history of abnormal heart rhythms (arrhythmias)
- have been diagnosed with an enlargement or “bulge” of a large blood vessel (aortic aneurysm or large vessel peripheral aneurysm)
- have experienced a previous episode of aortic dissection (a tear in the aorta wall)
- have a family history of aortic aneurysm or aortic dissection or other risk factors or predisposing conditions (e.g. connective tissue disorders such as Marfan syndrome or vascular Ehlers-Danlos syndrome, or vascular disorders such as Takayasu arteritis, giant cell arteritis, Behcet’s disease, high blood pressure or known atherosclerosis)

You should not take fluoroquinolone antibacterial medicines, including Enoxin Tablet 500mg, if you have experienced any serious adverse reaction in the past when taking a fluoroquinolone (see section Things to be careful of and Side effects). In this situation, you should inform your healthcare providers as soon as possible.

- Taking other medicines

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

The following medicines are known to interact with Enoxin in your body. Taking Enoxin together with these medicines can influence the therapeutic effect of those medicines. It can also increase the probability of experiencing side effects.

Tell your doctor if you are taking:

- warfarin or other oral anti-coagulants (blood thinning)
- probenecid (for gout)
- theophylline (for breathing problems)
- clozapine (an antipsychotic)
- ropinirole (for Parkinson’s disease)

- phenytoin (for epilepsy)

Enoxin may increase the levels of the following medicines in your blood:

- pentoxifylline (for circulatory disorders)
- caffeine

Some medicines reduce the effect of Enoxin. Tell your doctor if you take or wish to take:

- antacids
- mineral supplements
- sucralfate
- medicines or supplements containing calcium, magnesium, aluminium or iron

If these preparations are essential, take Enoxin about two hours before or no sooner than four hours after them.

How to use Enoxin

Swallow the tablets with plenty of fluid. Do not chew the tablets because they do not taste nice.

However, do not take Enoxin tablets with dairy products such as milk or yoghurt or with fortified fruit juices

- How much to use

Your doctor will explain to you exactly how much Enoxin you will have to take as well as how often and for how long.

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- When to use it

Use as directed by your doctor or pharmacist.

Do try to take the tablets at around the same time every day.

You can take the tablets at mealtimes or between meals. Any calcium you take as part of a meal will not seriously affect uptake.

- How long to use it

Usually the treatment will take for 5 to 21 days, but may take longer for severe infections.

Continue taking Enoxin for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of the nearest hospital, if you think you or anyone else may have taken too much of this medicine. If possible, take your tablets or the box with you to show the doctor.

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

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

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

Tell your doctor immediately if you become pregnant while taking this medication.

Stop taking Enoxin and contact your doctor immediately, if any of the following occurs while taking Enoxin. Your doctor will decide whether treatment with Enoxin needs to be stopped.

- Severe, sudden allergic reaction with the following symptoms: tightness in the chest, feeling dizzy, sick or faint,

or experiencing dizziness when standing up.

- Pain and swelling in the joints and tendon may occur occasionally, particularly if you are elderly and are also being treated with corticosteroids.
- If you suffer from epilepsy or stroke, you may experience side effects associated with the central nervous system.
- If you suffer from depression or psychosis, your symptoms may become worse.
- You may experience symptoms of neuropathy such as pain, burning, tingling, numbness and/or weakness.
- Diarrhoea may develop while you are taking antibiotics, including Enoxin, or even several weeks after you have stopped taking them. If it becomes severe or persistent or you notice that your stool contains blood or mucus, do not take medicines that stop or slow down bowel movements.
- If you notice any symptoms such as loss of appetite, jaundice (yellowing of the skin), dark urine, itching, or tenderness of the stomach.
- Enoxin may decrease number of white blood cells and your resistance to infection.

Tell the doctor or laboratory staff that you are taking Enoxin if you have to provide a blood or urine sample.

Tell your doctor if you or a member of your family is known to have a deficiency in glucose-6-phosphate dehydrogenase (G6PD), since you may experience a risk of anaemia with ciprofloxacin.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Enoxin to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Taking Enoxin with food and drink

Unless you take Enoxin during meals, do not eat or drink any dairy products (such

as milk or yoghurt) or drinks with added calcium when you take the tablets, as they may affect the absorption of the active substance.

If you feel sudden, severe pain in your abdomen, chest or back, go immediately to the emergency department.

Prolonged, disabling and potentially irreversible serious side effects

Fluoroquinolone antibacterial medicines, including Enoxin Tablet 500mg, have been associated with very rare but serious side effects, some of them being long lasting (continuing months or years), disabling or potentially irreversible.

Stop taking your fluoroquinolone antibiotic and contact your healthcare providers immediately if you have the following signs of a side effect:

- Tendon pain or swelling, often beginning in the ankle or calf. If this happens, rest the painful area until you see your healthcare providers.
- Pain in your joint or swelling in your shoulder, arms or legs.
- Abdominal pain or sensations (such as persistent pins and needles, tingling, numbness, or burning), weakness on your body, especially in the legs or arms, or difficulty walking.
- Severe tiredness, depressed mood, anxiety, problems with your memory, or severe problems sleeping.
- Changes in your vision, taste, smell or hearing

Tell your healthcare providers if you had one of the above effects during or shortly after taking a fluoroquinolone – this means you should avoid them in the future. You and your healthcare providers will decide on continuing the treatment considering also an antibiotic from another class.

Tendinitis and tendon rupture

Pain and swelling in the joints and inflammation or rupture of tendons may occur rarely. Your risk is increased if you are elderly (above 60 years of age), have received an organ transplant, have kidney problems or if you are being

treated with corticosteroids. Inflammation and ruptures of tendons may occur within the first 48 hours of treatment and even up to several months after stopping of Enoxin Tablet 500mg therapy. At the first sign of pain or inflammation of a tendon (for example in your ankle, wrist, elbow, shoulder or knee), stop taking Enoxin Tablet 500mg, contact your healthcare providers and rest the painful area. Avoid any unnecessary exercise as this might increase the risk of a tendon rupture.

Peripheral neuropathy

You may rarely experience symptoms of nerve damage (neuropathy) such as pain, burning, tingling, numbness and/or weakness especially in the feet and legs or hands and arms. If this happens, stop taking Enoxin Tablet 500mg and inform your healthcare providers immediately in order to prevent the development of potentially irreversible condition.

Psychiatric reactions

Psychiatric reactions may occur even after the first administration of fluoroquinolones, including Enoxin Tablet 50mg. In rare cases, depression or psychotic reactions can progress to suicidal ideations/thoughts and self-injurious behaviour, such as attempted or completed suicide (see section 'Undesirable effects'). In the event that the patient develops these reactions, Enoxin Tablet 50mg should be discontinued and appropriate measures instituted. Caution is recommended if Enoxin Tablet 50mg is to be used in psychotic patients or in patients with a history of psychiatric disease

Pregnancy and Breast-feeding

It is preferable to avoid the use of Enoxin during pregnancy. Tell your doctor if you are planning to get pregnant.

Do not take Enoxin during breast feeding because ciprofloxacin is excreted in breast milk and can be harmful for your child.

Driving and using machines

Enoxin may make you feel less alert. Some neurological adverse events can occur. Therefore, make sure you know how you react to Enoxin before driving a vehicle or operating machinery. If in doubt, talk

to your doctor.

Side effects

Like all medicines, Enoxin can cause side effects, although not everybody gets them. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

Common side effects:

- nausea, diarrhoea
- rash

Serious but very rare side effects:

- a special type of reduced red blood cell count (haemolytic anaemia); a dangerous drop in a type of white blood cells (agranulocytosis), a drop in the number of red and white blood cells and platelets (pancytopenia) and bone marrow depression,
- severe allergic reactions
- mental disturbances
- migraine, disturbed coordination, unsteady walk (gait disturbance), disorder of sense of smell, pressure on the brain (intracranial pressure)
- visual colour distortions
- inflammation of the wall of the blood vessels (vasculitis)
- pancreatitis
- death of liver cells very rarely leading to life-threatening liver failure
- small, pin-point bleeding under the skin (petechiae), various skin eruptions or rashes (for example, the potentially fatal Stevens-Johnson syndrome or toxic epidermal necrolysis)
- muscle weakness, tendon inflammation, tendon rupture – especially of the large tendon at the back of the ankle (Achilles tendon)
- worsening of the symptoms of myasthenia gravis

Fluoroquinolones have been reported to cause serious side effects involving tendons, muscles, joints and the nerves – in a small proportion of patients, these side effects caused long-lasting or permanent disability (see section Before you start to use it and Things to be careful of).

Visit your doctor or pharmacist immediately if you experience any side-effects after taking this medicine.

You may report any side effects or

adverse drug reactions directly to the National Centre for Adverse Drug Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicine (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Enoxin

- Storage

Keep them out of the reach of the children.

Do not store in temperature over 30°C. Keep it in its original pack. Protect it from light and humidity. Do not use it after its expiring date, recorded on the packaging.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

Product Description

- What it looks like

An oblong shape tablet, film coated white to off white, one side scored.

- Ingredients

- Active ingredient
Ciprofloxacin 500mg

- Inactive ingredients

- Povidone
- Croscarmellose Sodium
- Lactose Monohydrate
- Opadry White II
- Microcrystalline Cellulose
- Magnesium stearate

- MAL number

MAL05051054AZ

Manufacturer

Duopharma Manufacturing (Bangi) Sdn Bhd
Lot 2&4, Jalan P/7, Section 13,
Bangi Industrial Estate,
43650 Bandar Baru Bangi, Selangor
Darul Ehsan

Product Registration Holder

Duopharma Marketing Sdn Bhd
Lot 2, 4, 6, 8 & 10, Jalan P/7, Section 13,
Bangi Industrial Estate,
43650 Bandar Baru Bangi
Selangor Darul Ehsan

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