

CIPROXIN[®] SUSPENSION (Ci-PROX-in)

ciprofloxacin

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Ciproxin suspension. 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 Ciproxin suspension 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 CIPROXIN IS USED FOR

Ciproxin suspension is used for the treatment of infections of the lungs, skin, blood, bones, joints, kidneys, ovaries, fallopian tubes, bladder, genital organs, prostate, stomach and bowel. Ciproxin is also used to treat inhalational anthrax (an infection caused by breathing in the spores of the bacteria).

In children, Ciproxin suspension is used to treat lung infections caused by cystic fibrosis (a genetic disorder that affects the lungs and the digestive system), inhalational anthrax and serious

bacterial infections of the bladder and kidneys.

Ciproxin suspension contains the active ingredient, ciprofloxacin, which is an antibiotic belonging to a group of medicines called quinolones (pronounced kwin-olones). These antibiotics work by killing the bacteria that are causing your infection.

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

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.

BEFORE YOU TAKE CIPROXIN

When you must not take it

Do not take Ciproxin if you have an allergy to:

- ciprofloxacin, the active ingredient in Ciproxin
- any of the ingredients listed at the end of this leaflet
- other medicines belonging to the quinolone chemical family (e.g. moxifloxacin, norfloxacin, 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 Ciproxin if you are also taking a medicine called tizanidine, a muscle relaxant used to treat spasticity (stiffness or tightness of muscles) associated with multiple sclerosis, injury or diseases of the spinal cord. Ciproxin can interfere with tizanidine and can lead to unwanted side effects such as low blood pressure and drowsiness.

Do not take this medicine after the expiry date printed on the carton and bottle.

The expiry date is printed on the carton and on each bottle after "EXP" (e.g. 11 09 refers to November 2009). The expiry date refers to the last day of that month. If it has expired return it to your pharmacist for disposal.

Do not take this medicine if the packaging is torn or shows signs of tampering.

If the packaging 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 are pregnant or plan to become pregnant. Ciproxin should not be taken if you are pregnant. Medicines similar to Ciproxin have caused joint disease in immature animals.

Tell your doctor if you are breastfeeding.

Ciproxin is excreted into the breast milk and should not be taken if you are breastfeeding.

Ciproxin 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). Ciproxin 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. Ciproxin can worsen the symptoms of this condition
- have a history of tendon disorders with the use of quinolones (e.g. moxifloxacin, norfloxacin, nalidixic acid)
- currently have or have a history of depression or mental illness
- have diabetes. Fluoroquinolone antibiotics, including Ciproxin, may cause disturbances in blood sugar levels especially in elderly patients treated with oral medicines or insulin to lower the blood sugar. Your

doctor may wish to monitor your blood sugar during treatment with Ciproxin.

- have ever been told that you have an aortic aneurysm

Ciproxin suspension contains sucrose. Tell your doctor if you have an intolerance to some sugars.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking Ciproxin.

Taking other medicines

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

Some medicines may be affected by Ciproxin. These medicines include:

- medicines used to treat arrhythmias (fast or irregular heartbeats)
- theophylline, a medicine used to treat asthma
- oral anticoagulants, warfarin and its metabolites, medicines used to stop blood clots
- phenytoin, a medicine used to treat epilepsy
- oral antidiabetic medicines
- pentoxifylline, a medicine used to improve blood flow in patients with circulation problems
- cyclosporin, a medicine used to suppress the immune system
- non-steroidal anti-inflammatory agents (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
- sildenafil, a medicine used to treat erectile dysfunction
- agomelatine, a medicine used to treat depression
- zolpidem, a medicine to help you sleep

These medicines may be affected by Ciproxin, 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 Ciproxin. 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
- didanosine, a medicine used to treat Human Immunodeficiency Virus (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 or lanthanum carbonate, medicines 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 Ciproxin. However, you must take Ciproxin at least 2 hours before or 4 hours after taking any of these medicines.

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

HOW TO TAKE CIPROXIN

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 printed on the pharmacist label, 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 Ciproxin. This will depend on the type of infection and any medical conditions you may have.

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

When to take it

Ciproxin suspension is usually taken twice a day. Take the suspension at the same time each day preferably on an empty stomach. However, the suspension can be taken with or without food.

Take calcium supplements, multivitamins, antacids or dairy products at least 2 hours before or 4 hours after Ciproxin, as these can affect the absorption of Ciproxin and your medicine may not work properly.

How long to take it

The length of treatment may vary as it depends on the type of infection you have.

Continue taking Ciproxin until you have finished the suspension or for as long as your doctor tells you. Do not stop taking Ciproxin 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 it 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, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

WHILE YOU ARE TAKING CIPROXIN

Things you must do

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

Tell your doctor if you need to have a surgical or dental procedure that you are taking Ciproxin.

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

Drink plenty of water while you are taking Ciproxin. This helps to stop crystals forming in the urine.

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

If you develop diarrhoea, tell your doctor or pharmacist immediately - even if it occurs several weeks after you have stopped taking Ciproxin. Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care. Do not take any medications for diarrhoea without checking with your doctor or pharmacist.

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

Seek emergency medical help if you experience sudden stomach, chest or back pain

Things you must not do

Do not give Ciproxin suspension to anyone else, even if they have the same condition as you.

Do not use Ciproxin to treat other conditions unless your doctor tells you to.

Do not stop taking Ciproxin because you are feeling better, unless your doctor told you to do so. 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 up completely or it may return.

Things to be careful of

Avoid excessive exposure to direct sunlight. Your skin may become more prone to sunburn. If this occurs, tell your doctor immediately.

Be careful driving or operating machinery until you know how Ciproxin affects you. Ciproxin suspension may cause dizziness in some patients, especially after the first few doses. Your ability to drive and/or operate machinery may be impaired. If you drink alcohol while taking this medicine, dizziness may be worse.

Ciproxin may increase the stimulatory effects of caffeine.

IN CASE OF OVERDOSE

If you take too much (overdose)

Immediately telephone your doctor, or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to the Accident and Emergency department at your nearest hospital, if you think you or anyone else may have taken too much Ciproxin. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

SIDE EFFECTS

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

All medicines have side effects. Sometimes they are serious, most of the time they are not. In serious cases, you may need medical attention.

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 if you notice any of the following and they worry you:

- nausea
- diarrhoea

These are the common side effects of Ciproxin.

Tell your doctor immediately, or go to the Accident and Emergency department at your nearest hospital if you notice any of the following:

- sudden stomach, chest or back pain
- 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 Ciproxin suspension
- fits (seizures, convulsions)
- confusion, nightmares, hallucinations, and psychotic

reactions (even progressing to self-endangering behaviour)

- fast or irregular heart beats
- visual disturbances
- ringing in the ear, loss of hearing
- inflammation of the bowel, abdominal cramps. Very rarely this can progress to a serious condition accompanied by fever and fatigue.

If you have these side effects, you may need urgent medical attention.

In isolated instances, some serious adverse drug reactions may be long-lasting (> 30 days) and disabling; such as tendinitis, tendon rupture, musculoskeletal disorders, and other reactions affecting the nervous system including psychiatric disorders and disturbance of senses.

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

Ciproxin has been associated with side effects affecting the muscles. Rarely, there can be a 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 in speaking and swallowing, and sometimes muscle weakness in the arms or legs.

Rarely, Ciproxin can cause rupture of the tendons. Tendons are cords of tissue that join muscles and bones. Inflammation and rupture of tendons may occur even within the first 48 hours of treatment or up to several months after completing treatment with Ciproxin. The risk of inflammation and rupture of

tendons may be increased in elderly patients, during strenuous physical activity, if you are currently being treated with a type of medicine called corticosteroids, if you have impaired kidney function or if you have received solid organ transplants. Tell your doctor immediately if you feel any discomfort, pain or swelling.

Ciproxin has been associated with side effects affecting the nerves of the body including pain, burning, tingling and numbness or weakness of the body.

Rarely, Ciproxin can cause changes in mood and your thoughts.

Rarely, you may experience hyperglycaemia (high blood sugar). Symptoms include increased thirst, appetite and urination. Tell your doctor if you experience these symptoms.

You may also experience hypoglycaemia (low blood sugar). This may occur in diabetics who are also taking oral antidiabetic medicine. Symptoms include weakness, shaking, sweating, lightheadedness, dizziness, 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 with Ciproxin suspension, tell your doctor or pharmacist immediately. Ciproxin may need to be discontinued.

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 patients.

AFTER USING CIPROXIN

Storage

Keep the cap on the suspension until it is time to take it. If you leave the suspension uncapped, it may not keep well.

Keep your reconstituted (mixed) suspension in a cool dry place at room temperature up to 30°C or in the refrigerator for up to 14 days. Do not freeze the suspension.

Do not store Ciproxin or any other medicine in the bathroom, near a sink, or on a window sill.

Do not leave it in the car.

Heat and dampness can destroy some medicines.

Keep the suspension 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 Ciproxin or the suspension has passed the expiry date, ask your pharmacist what to do with the left over suspension.

Return any unused medicine to your pharmacist.

PRODUCT DESCRIPTION

What it looks like

Ciproxin suspension comes in two bottles with a 5 mL measuring spoon. The smaller bottle contains the granules, which you add to the solution in the larger bottle.

The Ciproxin microcapsules are white to slightly yellowish granules and the suspension

diluent is white to slightly yellowish fluid.

The reconstituted (mixed) Ciproxin suspension is a white to slightly yellowish suspension with a strawberry flavour. It may also contain yellow-orange droplets.

Instructions for use/handling

1. Open both bottles by pressing down on the childproof cap while turning the cap to the left.
2. Empty the granules into the larger bottle. Do not pour water into the suspension.
3. Replace the cap on the larger bottle properly and shake vigorously for about 15 seconds. The reconstituted (mixed) suspension is now ready to use.
4. Take the prescribed amount of the reconstituted (mixed) suspension by using the measuring spoon provided. Swallow the granules present in the suspension, do not chew them. A drink of water may be taken afterwards. Replace the cap on the bottle after use.
5. Clean the measuring spoon under running water with detergent, rinse with water and dry thoroughly afterwards.

The reconstituted (mixed) suspension may be stored at room temperature up to 30°C or kept in the refrigerator for up to 14 days. Do not freeze the reconstituted (mixed) suspension. After treatment has been completed, discard any excess suspension.

Shake well each time before use for approximately 15 seconds.

Ingredients

Active Ingredient:

- Ciproxin suspension 5 g/100 mL – 5 mL contains 250 mg ciprofloxacin
- Ciproxin suspension 10 g/100 mL – 5 mL contains 500 mg ciprofloxacin

Inactive ingredients:

- copolymer of ethyl acrylate and methyl methacrylate
- magnesium stearate
- methylhydroxypropyl-cellulose

- polysorbate
- polyvidone
- lecithin
- sucrose
- strawberry flavour
- medium chain triglycerides
- water

SPONSOR DETAILS

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