

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

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

Ciproxin IV is used to treat serious infections in the lungs, skin, blood, bone, joints, kidneys, and bowel. Ciproxin IV is also used to treat inhalational anthrax (an infection caused by breathing in the spores of bacteria).

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

Ciproxin IV is used in hospitalised patients where use of Ciproxin tablets is inappropriate.

Ciproxin IV 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 ARE GIVEN CIPROXIN IV

When you must not be given it

You must not be given Ciproxin IV if you have an allergy to:

- ciprofloxacin, the active ingredient in Ciproxin IV
- 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 use Ciproxin IV 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).

Ciproxin IV can interfere with tizanidine and can lead to undesirable side effects.

Do not use this medicine after the expiry date printed on the pack and vial.

The expiry date is printed on the carton and on each vial after "EXP" (e.g. 11 13 refers to

November 2013). The expiry date refers to the last day of that month. If it has expired return it to the 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.

The contents of the vial are not to be used if it is cloudy or has little specks in it.

If you are not sure whether you should be given this medicine, talk to your doctor.

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

Tell your doctor if you are breastfeeding.

Ciproxin is excreted into the breast milk. Your doctor will tell you whether you should take it and temporarily stop breastfeeding while you are receiving Ciproxin IV.

Ciproxin IV is not recommended in children under 18 years of age except for use in inhalational anthrax.

Ciproxin IV 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 IV 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 congestive heart failure, renal failure, nephrotic syndrome. Sodium intake may be of medical concern and the additional sodium load from using Ciproxin IV should be taken into account
- have myasthenia gravis, a condition where the muscles become weak. Ciproxin IV can worsen the symptoms of this condition
- have a history of tendon disorders with the use of quinolones (e.g. moxifloxacin, norfloxacin, nalidixic acid)

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

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 may be affected by Ciproxin IV. These include:

- medicines used to treat arrhythmias (fast or irregular heartbeats)
- theophylline, a medicine used to treat asthma
- oral anticoagulants, warfarin and its derivatives, medicines used to stop blood clots
- phenytoin, a medicine used to treat epilepsy
- oral antidiabetic agents cyclosporin, a medicine used to suppress the 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 Ciproxin IV, 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 Ciproxin IV. These include:

- probenecid, a medicine used to treat gout
- omeprazole, a medicine used to treat stomach ulcers and other conditions where stomach produces too much acid

You can still take these medicines while you are receiving Ciproxin IV.

However, you must use Ciproxin IV at least 2 hours before or 2 hours after taking any of these medicines.

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

HOW CIPROXIN IV IS GIVEN

Ciproxin IV is given as a slow injection into a vein over a period of 60 minutes, usually as a drip, by a doctor or a nurse.

How much to receive

This depends on your condition, and will be decided by your doctor. The usual adult dose is 200-300 mg twice a day for one to two weeks. Normally your doctor will put you on

antibiotic tablets as soon as possible; but for difficult infections longer intravenous therapy may be required.

If you have not been given the next dose, tell the doctor or nurse on duty as soon as possible.

If you are given too much (overdose)

Immediately tell your doctor or nurse on duty or telephone your doctor, or the Poisons Information Centre (telephone in Australia 13 11 26, in New Zealand 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 received too much Ciproxin IV. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

WHILE YOU ARE RECEIVING CIPROXIN IV

Things you must do

Tell all doctors, dentists, nurses and pharmacists who are treating you that you are receiving Ciproxin IV.

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

The use of Ciproxin IV may affect the results of certain laboratory tests.

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

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

Drink plenty of water while you are receiving Ciproxin IV.

This helps to stop crystals forming in your urine.

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

If you develop diarrhoea, tell your doctor or pharmacist immediately – even after you have stopped receiving Ciproxin IV. 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 first checking with your doctor or pharmacist.

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

Ciproxin IV should be discontinued immediately.

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

Things you must not do

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

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

Do not stop using Ciproxin IV 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.

What to be careful of

Avoid excessive exposure to direct sunlight.

Your skin may become more prone to sunburn. If such a reaction occurs, tell your doctor.

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

Ciproxin IV 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 using this medicine, dizziness may be worse.

Ciproxin IV may increase the stimulatory effects of caffeine.

SIDE EFFECTS

Tell your doctor or nurse as soon as possible if you do not feel well while you are receiving Ciproxin IV.

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

Ciproxin IV is usually well tolerated.

Do not be alarmed by the following lists of side effects. You may not experience any of them. Ask your doctor to answer any questions you may have.

Ciproxin IV can cause redness, pain, and inflammation at the injection site.

Vomiting and rash were common in patients switching from Ciproxin IV to Ciproxin tablets.

Tell your doctor if you notice any of the following and they worry you:

- nausea
- diarrhoea

These are the common side effects of Ciproxin IV. They are usually mild and short-lived.

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

- 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 receiving Ciproxin IV
- fits (seizures, convulsions)
- confusion, nightmares, hallucinations, and psychotic reaction (even progressing to self-endangering behaviour)
- fast or irregular heart beats
- visual disturbances (eyesight problems)
- 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.

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

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

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, the Achilles tendon (extending from the calf to the heel of the foot) or other tendons have been torn after Ciproxin IV therapy. Tell your doctor immediately if you feel any discomfort, pain, 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. Tell your doctor if you experience these symptoms.

If you experience any of these symptoms during the treatment with Ciproxin IV, tell your doctor, nurse or pharmacist immediately. Ciproxin IV may need to be discontinued.

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

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

AFTER RECEIVING CIPROXIN IV

When treatment is to be stopped, your prescribing doctor may need to alter the dose of other medicine(s) accordingly and monitor your condition.

Each vial of Ciproxin IV is to be used once only. Any unused portion remaining in the vial must be discarded.

Storage

Ciproxin IV will be stored in the pharmacy or on the ward. The vial should not be stored in the refrigerator.

Keep your medicine in the carton until it is time to use them.

If you take the vial out of the box they may not keep well.

Keep your medicine in a cool, dry place (away from sunlight) where the temperature stays below 30°C.

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

Do not leave it in the car.

Heat and damp can destroy some medicines.

Keep the medicine where children cannot reach them.

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 IV or your medicine has passed their expiry date, ask your pharmacist what to do with any that are left over.

Return any unused medicine to your pharmacist.

PRODUCT DESCRIPTION

What it looks like

Ciproxin IV is a clear isotonic solution containing ciprofloxacin in the following strengths:

- 100 mg/50 mL vial (available in Australia only)
- 200 mg/100 mL vial

Ingredients

Active Ingredient:

- Ciproxin IV 100 – 100 mg ciprofloxacin (as lactate)/50 mL vial
- Ciproxin IV 200 – 200 mg ciprofloxacin (as lactate)/100 mL vial

Inactive ingredients:

- lactic acid
- sodium chloride
- water for injection
- small amounts of hydrochloric acid to adjust the acidity of the solution.

Supplier

Made in Germany for:

Bayer Australia Limited
ABN 22 000 138 714
875 Pacific Highway
Pymble NSW 2073

Bayer New Zealand Limited
3 Argus Place, Hillcrest
North Shore Auckland 0627
Free phone 0800 233 988

Australian Registration Numbers

Ciproxin IV 100 - AUST R 43098
Ciproxin IV 200 - AUST R 43099

Date of preparation

July 2017

See TGA website (www.tga.gov.au) for latest Australian Consumer Medicine Information.

See MEDSAFE website

(www.medsafe.govt.nz) for latest New Zealand Consumer Medicine Information.

® Registered Trademark of Bayer Group, Germany

© Bayer Australia Ltd All rights reserved.

