

ASPEN CIPROFLOXACIN Injection for Intravenous Infusion

ciprofloxacin

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ASPEN CIPROFLOXACIN Injection for Intravenous Infusion. 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 being given ASPEN CIPROFLOXACIN Injection for Intravenous Infusion against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What ASPEN CIPROFLOXACIN Injection for Intravenous Infusion is used for

ASPEN CIPROFLOXACIN Injection for Intravenous Infusion contains ciprofloxacin (as ciprofloxacin lactate) as the active ingredient. It belongs to a group of antibiotics called fluoroquinolones.

This medicine is used to treat many different conditions including:

- lung infections
- infections of skin

- infections of bone and joints
- kidney and bladder infections
- infections in the blood
- inhalation of anthrax (post-exposure).

It works by killing many kinds of bacteria which cause infections in the body.

Ciprofloxacin will not work against infections caused by viruses such as cold and 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.

It is available only with a doctor's prescription.

There is no evidence that it is addictive.

Before you are given it

When you must not be given it

You must not be given this medicine if you have an allergy to:

- ciprofloxacin
- any other quinolone antibiotics such as grepafloxacin, moxifloxacin, nalidixic acid or norfloxacin
- any of the ingredients listed at the end of this leaflet.

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 have this medicine if you are also taking a medicine called tizanidine.

You must not be given this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

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 have or have had any of the following medical conditions:

- epilepsy or seizures or fits
- myasthenia gravis (a condition of extremely weak muscles)
- kidney disease
- liver disease
- if you or your family have or have had any heart-related conditions, including heart-valves, or conditions affecting the veins or arteries such as Takayasu arteritis, giant cell arteritis, atherosclerosis, Behcet's disease
- Sjögren's syndrome
- high blood pressure
- diarrhoea
- decreased blood flow to parts of the brain (stroke)
- tendon pain, inflammation or rupture of tendons or a history

of tendon problems associated with quinolone antibiotics

- connective tissue disorders such as Marfan syndrome, Ehlers-Danlos syndrome, Turner syndrome, rheumatoid arthritis
- sensitivity of the skin to sunlight
- diabetes mellitus or sugar diabetes (too much sugar in the blood)
- solid organ transplant.

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

- Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you have previously taken or currently taking corticosteroids such as prednisolone or cortisone.

You may be at increased risk of aortic aneurysm and dissection and swelling of the tendons.

Symptoms of aortic aneurysm and dissection include sudden, severe pain in your abdomen, chest or back.

Symptoms of swelling of the tendons include pain, tenderness and sometimes restricted movement.

Use in children

The use of this medicine in infants, children or growing teenagers is not recommended since fluoroquinolones may cause bone development problems. However, your doctor may choose to use this medicine if other medicines cannot be used.

If you have not told your doctor about any of the above, tell them before you start being given this medicine.

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 ciprofloxacin may interfere with each other.

These include:

- medicines used to treat arrhythmias (fast or irregular heartbeats)
- theophylline, a medicine used to treat asthma
- glibenclamide or gliclazide, oral medicines used to treat diabetes
- cyclosporin, an immunosuppressant
- warfarin or anticoagulants, medicines used to stop the clotting of blood
- non-steroidal anti-inflammatory drugs (NSAIDs), that are used for pain and inflammation
- probenecid, a medicine used for gout
- caffeine found in coffee, cola and some medications
- methotrexate, a medicine used to treat certain types of cancers, severe psoriasis and severe rheumatoid arthritis
- omeprazole, a medicine used to treat stomach ulcers and reflux
- duloxetine, a medicine used to treat depression, anxiety and nerve pain due to high blood sugar levels
- clozapine, a medicine used to treat schizophrenia
- lidocaine (lignocaine), a local anaesthetic
- ropinirole, a medicine used to treat Parkinson's disease and restless legs syndrome
- pentoxifylline (oxypentifylline), a medicine used to improve the circulation of the blood
- phenytoin, a medicine used to treat epilepsy and irregular heart beats
- sildenafil, a medicine used to treat erectile dysfunction
- zolpidem, a medicine used to treat sleep disorders
- antibiotics known as macrolides (eg clarithromycin,

roxithromycin, azithromycin and erythromycin)

- some medicines used to treat depression (eg agomelatine, imipramine, amitriptyline, clomipramine)
- some antipsychotics, (medicines used to treat certain mental and emotional conditions).

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

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

How it is given

How much is given

Your doctor will decide what dose you will receive. This depends on the condition being treated and your response to the treatment.

How it is given

ASPEN CIPROFLOXACIN Injection for Intravenous Infusion is given as a slow infusion, over a period of not less than 60 minutes, into a vein. It must only be given by a nurse or doctor.

If you receive too much (overdose)

As ASPEN CIPROFLOXACIN Injection for Intravenous Infusion is given to you in a hospital under the supervision of your doctor, it is very unlikely that you will be given too much.

However if you experience any side effects after being given it, tell your doctor or nurse immediately.

While you are being given it

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being given ASPEN CIPROFLOXACIN Injection for Intravenous Infusion.

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

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

It may affect other medicines used during surgery.

If you are about to have any blood tests, tell your doctor that you are being treated with this medicine.

It may interfere with the results of some tests.

If you get severe diarrhoea, tell your doctor or nurse immediately. Do this even if it occurs several weeks after this medicine has been stopped. Do not take any diarrhoea medicine without first checking with your doctor.

Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care.

If you become pregnant while you are being treated with this medicine, tell your doctor immediately.

Drink plenty of water while you are being treated with this medicine.

This will help prevent crystals forming in the urine.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

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

Things to be careful of

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

This medicine may cause dizziness, light-headedness, tiredness and drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while you are being given this medicine.

If you drink alcohol, dizziness or light-headedness may be worse.

This medicine may increase the stimulatory effects of caffeine.

Protect your skin when you are in the sun and avoid direct sunlight if possible. If outdoors, wear protective clothing.

This medicine may cause your skin to be much more sensitive to sunlight than it is normally.

Exposure to sunlight may cause a skin rash, itching, redness, or a severe sunburn.

If your skin does appear to be burning, see your doctor as soon as possible. You may need alternative treatment.

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well while you are being treated with ASPEN CIPROFLOXACIN Injection for Intravenous Infusion.

This medicine helps most people with 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 attention 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 lists of side effects.

You may not experience any of them.

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

Tell your doctor, nurse or pharmacist if you notice any of the following and they worry you:

- headache
- fever
- dizziness or light-headedness
- mild stomach upsets such as stomach pains, flatulence or diarrhoea
- loss of appetite or altered taste
- heartburn (dyspepsia)
- nausea or vomiting
- irritability, agitation or confusion
- difficulty sleeping.

The above list includes the more common side effects of your medicine.

Tell your doctor as soon as possible if you notice any of the following:

- pain, swelling, redness or tenderness at site of injection.
- increased feeling of sensitivity, such as pain, burning, tingling or numbness and/or muscle weakness
- anxiety or nervousness
- pain inflammation or rupture of the Achilles tendon (which extends from the calf to the heel of the foot) or other tendons
- increased sensitivity of the skin to sunlight, resulting in getting sunburnt more easily than usual
- symptoms of low blood sugar level (hypoglycaemia), which may include sweating, weakness, hunger, dizziness, trembling, headache, flushing or

- paleness and fast, pounding heart beat
- symptoms of high blood sugar (hyperglycaemia), which may include passing large amounts of urine, excessive thirst and having a dry mouth and skin.

The above list includes serious side effects which may require medical attention.

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

- swelling of the face, lips, mouth or throat
- fainting
- wheezing or difficulty breathing
- severe skin rash, hives, itching or blistering or peeling of the skin
- severe abdominal or stomach cramps, swelling of the abdomen or lower extremities (hips down to your toes)
- sudden, severe pain in your abdomen, chest, back, which can be symptoms of aortic aneurysm and dissection
- severe watery or bloody diarrhoea, even if it occurs several weeks after you have stopped taking this medicine
- fits (convulsions or seizures)
- depression, confusion, hallucinations or paranoia, self-endangering thoughts, psychosis – a severe mental condition in which the person loses contact with reality and is unable to think and judge clearly or behaviour
- yellowing of the skin or eyes, also called jaundice
- 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

- palpitations or fast or irregular heart beats
- joint/muscle pain or cramping
- visual disturbances
- ringing in the ear, loss of hearing
- passing little or no urine
- dark coloured urine.

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

Tell your doctor if you notice anything else that is making you feel unwell, even if you think the problems are not connected with this medicine and are not referred to in this leaflet.

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

After using it

Storage

ASPEN CIPROFLOXACIN Injection for Intravenous Infusion will be stored in the hospital pharmacy or on the ward. The medicine is kept in a cool dry place, protected from light where the temperature stays below 25°C.

Product description

What it looks like

ASPEN CIPROFLOXACIN Injection for Intravenous Infusion is a clear, colourless to slightly yellow solution (0.2% w/v) available in either 50 mL or 100 mL infusion bags.

Available in packs of 10 infusion bags.

Ingredients

Active ingredient:

Each infusion bag contains 2 mg/mL (0.2% w/v) of ciprofloxacin.

Inactive ingredients:

- glucose monohydrate
- lactic acid
- water for injections.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

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Australian Registration Numbers:
100 mg/50 mL: AUST R 114731
200 mg/100 mL: AUST R 114735

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