ASPEN CIPROFLOXACIN solution for injection

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

WARNING: Important safety information is provided in a boxed warning in the full CMI. Read before using this medicine.

1. Why am I being given ASPEN CIPROFLOXACIN?

ASPEN CIPROFLOXACIN contains the active ingredient ciprofloxacin (as ciprofloxacin lactate). ASPEN CIPROFLOXACIN is used to treat a range of different bacterial infections.

For more information, see Section 1. Why am I being given ASPEN CIPROFLOXACIN? in the full CMI.

2. What should I know before I am given ASPEN CIPROFLOXACIN?

You should not be given ASPEN CIPROFLOXACIN if you have ever had an allergic reaction to ciprofloxacin, any other quinolone antibiotics, or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I am given ASPEN CIPROFLOXACIN? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ciprofloxacin and affect how it works.
A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How is ASPEN CIPROFLOXACIN given?

ASPEN CIPROFLOXACIN 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. Your doctor will decide what dose you receive.
More instructions can be found in Section 4. How is ASPEN CIPROFLOXACIN given? in the full CMI.

5. What should I know while I am being given ASPEN CIPROFLOXACIN?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using ASPEN CIPROFLOXACIN. • Drink plenty of water while you are being treated with ASPEN CIPROFLOXACIN. • Keep all of your doctor's appointments so that your progress can be checked. • Tell your doctor straight away if you become pregnant while being treated with this medicine.
Things you should not do	• 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 • Do not have this medicine if you are also taking a medicine called tizanidine
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how ASPEN CIPROFLOXACIN affects you. It may cause dizziness, light-headedness, tiredness and drowsiness in some people.
Drinking alcohol	• Be careful when drinking alcohol while you are being given this medicine. If you drink alcohol, dizziness or light-headedness may be worse.
Looking after your medicine	• This medicine is usually 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.

For more information, see Section 5. What should I know while being given ASPEN CIPROFLOXACIN? in the full CMI.

6. Are there any side effects?

Mild side effects of ASPEN CIPROFLOXACIN include headache, fever, dizziness or light-headedness, mild stomach upsets (e.g. stomach pains, flatulence or diarrhoea), loss of appetite or altered taste, heartburn (dyspepsia), nausea or vomiting, irritability, agitation or confusion, or difficulty sleeping. Serious side effects of ASPEN CIPROFLOXACIN may also occur. A list of these can be found in the full CMI.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

WARNINGS
Serious disabling and potentially irreversible side effects.
Some serious side effects may be long-lasting and disabling, such as tendonitis, tendon rupture, musculoskeletal disorders and other reactions affecting the nervous system including mental health disorders and disturbance of senses.

ASPEN CIPROFLOXACIN solution for injection

Active ingredient: *ciprofloxacin*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ASPEN CIPROFLOXACIN solution for injection.

You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ASPEN CIPROFLOXACIN.

Where to find information in this leaflet:

1. Why am I being given ASPEN CIPROFLOXACIN?
2. What should I know before I am given ASPEN CIPROFLOXACIN?
3. What if I am taking other medicines?
4. How is ASPEN CIPROFLOXACIN given?
5. What should I know while being given ASPEN CIPROFLOXACIN?
6. Are there any side effects?
7. Product details

1. Why am I being given ASPEN CIPROFLOXACIN?

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

ASPEN CIPROFLOXACIN is used to treat many different conditions including:

- lung infections
- infections of the 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. ASPEN 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.

2. What should I know before I am given ASPEN CIPROFLOXACIN?

Warnings

You should not be given ASPEN CIPROFLOXACIN if:

- **you are allergic to ciprofloxacin, any other quinolone antibiotics (e.g. grepafloxacin, moxifloxacin, nalidixic acid, or norfloxacin), or any of the ingredients listed at the end of this leaflet.**
  Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty in breathing; swelling of the face, lips, tongue, or any other parts of the body; rash, itching or hives on the skin.
- **you are also taking a medicine called tizanidine.**
- **the expiry date on the pack has passed**
- **the package shows signs of tampering.**

Check with your doctor if you:

- **have any other medical conditions, especially the following:**
  - 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 arthritis, 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.
- **take any medicines for any other condition**
- **have previously taken or are 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.
- swelling of the tendons include pain, tenderness and sometimes restricted movement.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

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.

3. What if I am taking other medicines?

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

Some medicines and ASPEN 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 glimepiride, 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ASPEN CIPROFLOXACIN.

4. How is ASPEN CIPROFLOXACIN 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 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 ASPEN CIPROFLOXACIN

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

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

5. What should I know while being given ASPEN CIPROFLOXACIN?

Things you should do

- **If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being given ASPEN CIPROFLOXACIN.**
- **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.**
- **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.

Call your doctor straight away if you:

- **Develop severe diarrhoea. Contact your doctor even if this condition 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.
- **Become pregnant while you are being treated with this medicine.**
- **Are experiencing symptoms of depression or self-endangering thoughts or behaviour.**

Remind any doctor, dentist or pharmacist you visit that you are using ASPEN CIPROFLOXACIN.

Things to be careful of

- This medicine may increase the stimulatory effects of caffeine.
- This medicine may cause your skin to be much more sensitive to sunlight than it is normally.
  Protect your skin when you are in the sun and avoid direct sunlight if possible. If outdoors, wear protective clothing.
  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.

Driving or using machines

Be careful before you drive or use any machines or tools 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.

Drinking alcohol

Tell your doctor if you drink alcohol.

Be careful when drinking alcohol while you are being given this medicine. If you drink alcohol, dizziness or light-headedness may be worse.

Looking after your medicine

- ASPEN CIPROFLOXACIN 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.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• 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.	**Speak to your doctor if you have any of these less serious side effects and they worry you.** These are common side effects of this medicine.

Serious side effects

Serious side effects	What to do
• 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.	**Tell your doctor as soon as possible if you notice any of these serious side effects. You may need medical attention.**
• swelling of the face, lips, mouth or throat • fainting • wheezing, difficulty breathing, shortness of breath	**Tell your doctor immediately or go straight to the Emergency**

• 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) • tremor • 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 • insomnia/nightmares, impaired memory • yellowing of the skin or eyes, also called jaundice • visual disturbances • 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 • chest pain, shortness of breath • joint/muscle pain or cramping • ringing in the ear, loss of hearing • passing little or no urine • dark coloured urine.	**Department at your nearest hospital if you notice any of these serious side effects. You may need urgent medical attention or hospitalisation.** These side effects are very rare.

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

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

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What ASPEN CIPROFLOXACIN contains

Active ingredient (main ingredient)	ciprofloxacin (as ciprofloxacin lactate): 200 mg/100 mL infusion bag
Other ingredients (inactive ingredients)	• glucose monohydrate • lactic acid • water for injections.

Contains no antimicrobial preservative.

Do not use this medicine if you are allergic to any of these ingredients.

What ASPEN CIPROFLOXACIN solution for injection looks like

ASPEN CIPROFLOXACIN solution for injection is a clear, colourless to slightly yellow solution (0.2% w/v) available in 100 mL infusion bags. Available in packs of 10 infusion bags.

Australian Registration number: AUST R 114735

Who distributes ASPEN CIPROFLOXACIN

Aspen Pharmacare Australia Pty Ltd
Sydney NSW
Australia

www.aspenpharma.com.au

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