ASPEN CIPROFLOXACIN

Injection for Intravenous Infusion

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. 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
- arrhythmias (fast or irregular heartbeats), especially if you are elderly or have low potassium levels
- myasthenia gravis (a condition of extremely weak muscles)
- kidney disease
- liver disease
- diarrhoea
- decreased blood flow to parts of the brain (stroke)
- tendon pain, inflammation or rupture of tendons
- sensitivity of the skin to sunlight
- diabetes mellitus.

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 are elderly and have previously taken corticosteroids such as prednisolone or cortisone.

You may be at increased risk of swelling of the tendons. Symptoms 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, a medicine used to treat diabetes
- cyclosporin, an immunosuppressant
- warfarin, a medicine 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.

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 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.

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.

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.

Protect yourself from the sun while you are being given this medicine.

If you go out in the sun, wear a hat, protective clothing and use sunscreen.

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 elderly you may have an increased chance of getting side effects.

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:

- nausea
- vomiting
- mild rash
- mild diarrhoea
- heartburn or mild abdominal pain

- agitation or restlessness
- headache
- pain, swelling, redness or tenderness at site of injection.

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:

- dizziness or light headednesstremor or weakness
- · rash or itchiness
- · vaginal itching or discharge
- · sore white mouth or tongue
- fever
- altered vision
- confusion
- difficulty walking
- dry mouth
- difficulty in swallowing
- flatulence
- constipation
- · loss of appetite
- getting sunburnt very easily
- nightmares
- tremors.

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:

- inflamed, painful or ruptured joints or tendons such as the Achilles tendon
- severe watery or bloody diarrhoea, even if it occurs several weeks after you have stopped taking this medicine
- severe stomach cramps
- palpitations or fast or irregular heart beats
- chest pain or angina
- · dark coloured urine
- yellowing of the skin or eyes, also called jaundice
- hallucinations
- fits (convulsions or seizures)

 signs of an allergic reaction such as shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; severe rash, itching or hives on the skin.

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.

Do not be alarmed by this list of side effects.

You may not experience any of them.

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
- lactic acid
- water for injections.

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

Sponsor

Aspen Pharmacare Australia Pty Ltd

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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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