

DBL™ Ciprofloxacin Injection for Intravenous Infusion

Ciprofloxacin

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DBL 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 DBL 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.

You may need to read it again.

What DBL Ciprofloxacin Injection for Intravenous Infusion is used for

This medicine is used to treat:

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

This medicine belongs to a group of medicines called fluoroquinolones.

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

DBL Ciprofloxacin Injection for Intravenous Infusion 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.

This medicine is not addictive.

It is available only with a doctor's prescription.

Before you are given DBL Ciprofloxacin Injection for Intravenous Infusion

When you must not be given it

You must not be given DBL Ciprofloxacin Injection for Intravenous Infusion if you have an allergy to:

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

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 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 it has expired or is damaged return it to your pharmacist for disposal.

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 your family have or have had any heart-related conditions, 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)
- 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.

DBL Ciprofloxacin Injection for Intravenous Infusion should not be used in children and growing teenagers except for use in inhalational anthrax.

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.

If you have not told your doctor about any of the above, tell him/her before you are given DBL Ciprofloxacin Injection for Intravenous Infusion.

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 DBL Ciprofloxacin Injection for Intravenous Infusion may interfere with each other. These include:

- theophylline, a medicine used to treat asthma
- oral medicines used to treat diabetes (eg glibenclamide and gliclazide)
- ciclosporin, an immunosuppressant
- warfarin or anticoagulants, medicines used to stop the clotting of blood
- non-steroidal anti-inflammatory drugs (NSAIDs), medicines 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
- some antiarrhythmics (medicines used to treat irregular or rapid heartbeats)
- 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 DBL Ciprofloxacin Injection for Intravenous Infusion 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 DBL Ciprofloxacin Injection for Intravenous Infusion is given

How much is given

Your doctor will decide what dose you will receive. This depends on your condition and other factors, such as your age and weight.

How it is given

DBL Ciprofloxacin Injection for Intravenous Infusion is given as a slow infusion (drip) into a vein. It must only be given by a nurse or doctor.

If you receive too much (overdose)

As DBL 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 receive an overdose. However, if you or anyone else experience severe side effects tell your doctor immediately or telephone the Poisons Information Centre 13 11

26 for advice, or go to Emergency at the nearest hospital.

You may need urgent medical attention.

Symptoms of an overdose may include the side effects listed below in the 'Side Effects' section but are usually of a more severe nature.

Ask your doctor or pharmacist if you have any concerns.

While you are being given DBL Ciprofloxacin Injection for Intravenous Infusion

Things you must do

If you are about to be started on any new medicine, remind your doctor or pharmacist you are being given DBL 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 DBL Ciprofloxacin Injection for Intravenous Infusion 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 DBL Ciprofloxacin Injection for Intravenous Infusion.

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 DBL Ciprofloxacin Injection for Intravenous Infusion 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.

DBL Ciprofloxacin Injection for Intravenous Infusion 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 DBL 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 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)
- feeling sick (nausea) or vomiting
- irritability, agitation or confusion
- difficulty sleeping.

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

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

- pain, redness or swelling at the site of the 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 (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.

If any of the following happen, tell your doctor or nurse immediately, or go to Emergency at your nearest hospital:

- swelling of the face, lips, mouth or throat
- fainting
- wheezing or difficulty breathing
- severe skin rashes, 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 or back, which can be symptoms of aortic aneurysm and dissection
- severe, watery or bloody diarrhoea, even if it occurs several weeks after stopping this medicine
- fits (seizures or convulsions)
- 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 and/or eyes, also called jaundice
- fast or irregular heart beats, also called palpitations
- 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, nurse or pharmacist if you notice anything that is making you feel unwell.

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

After using DBL Ciprofloxacin Injection for Intravenous Infusion

Storage

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

Product description

What it looks like

DBL Ciprofloxacin Injection for Intravenous Infusion is a clear, colourless to slightly yellow solution in an infusion bag.

DBL Ciprofloxacin Injection is supplied in infusion bags containing 100 mg/50 mL ciprofloxacin in

packs of 5, 10 and 50; 200 mg/100 mL ciprofloxacin in packs of 5, 10 and 50; and 400 mg/200 mL ciprofloxacin in packs 5, 10 and 20*.

*Not all pack sizes are available.

Ingredients

DBL Ciprofloxacin Injection for Intravenous Infusion contains 2 mg/mL of ciprofloxacin (as ciprofloxacin lactate) as the active ingredient.

It also contains:

- glucose monohydrate
- lactic acid
- hydrochloric acid (if required to adjust acidity)
- water for injections.

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

Supplier

Pfizer Australia Pty Ltd
Sydney NSW
Toll Free Number: 1800 675 229
www.pfizer.com.au

Australian Registration Number:

- 100 mg/50 mL bag AUST R 123038
- 200 mg/100 mL bag AUST R 123041
- 400 mg/200 mL bag AUST R 123042.

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