

DBL™ Cefepime Powder for Injection

Cefepime dihydrochloride (SEF-eh-pim)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DBL™ Cefepime Powder for Injection. It does not contain all the available information.

It does not take the place of talking to your doctor and pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Cefepime Powder for Injection against the benefits this medicine is expected to 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 DBL™ Cefepime Powder for Injection is used for

DBL™ Cefepime Powder for Injection belongs to a group of antibiotics called cephalosporins.

It is used to treat infections in different parts of the body caused by bacteria. These antibiotics work by killing the bacteria that are causing your infection.

DBL™ Cefepime Powder for Injection is an injectable antibiotic used for serious infections in adults caused by bacteria:

- in the lungs (pneumonia and bronchitis),
- in the kidney and bladder (urinary tract infections),

- in the skin,
- inside the abdomen (peritonitis and biliary tract infections),
- in the womb or vagina, or
- in the blood (septicaemia).

DBL™ Cefepime Powder for Injection is also used to prevent infections before, during and after surgery. It may be given before surgery or if you have a lack of white blood cells with fever.

DBL™ Cefepime Powder for Injection is also used for serious infections in children over 2 months of age caused by bacteria:

- in the lungs (pneumonia),
- in the kidney and bladder (urinary tract infections),
- in the skin;
- in the blood; or
- if the child has a lack of white blood cells with fever.

DBL™ Cefepime Powder for Injection will not work against infections caused by viruses such as colds or the flu.

Your doctor may have prescribed DBL™ Cefepime Powder for Injection for another reason.

Ask your doctor if you have any questions about why DBL™ Cefepime Powder for Injection has been prescribed for you.

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

DBL™ Cefepime Powder for Injection is not addictive.

Before you are given DBL™ Cefepime Powder for Injection

When you must not be given it

You must not be given DBL™ Cefepime Powder for Injection if:

- **you have an allergy to DBL™ Cefepime Powder for Injection, other cephalosporins or any of the ingredients listed at the end of this leaflet.**

Some of the symptoms of an allergic reaction may include skin rash, itching or difficulty breathing.

- **you have had a serious allergic reaction to penicillins.**

Do not use DBL™ Cefepime Powder for Injection if the packaging is torn or shows signs of tampering.

If you are not sure whether you should be given DBL™ Cefepime Powder for Injection, talk to your doctor.

Before you are given it

Tell your doctor if you have any allergies to:

- penicillin medicines.
- any other medicines
- any other substances, such as foods, preservatives or dyes

Tell your doctor if you are pregnant, or intend to become pregnant.

Your doctor will discuss with you the possible risks and benefits of using DBL™ Cefepime Powder for Injection during pregnancy.

Tell your doctor if you are breast-feeding or intend to breast-feed.

DBL™ Cefepime Powder for Injection may pass into breast milk and may affect your baby. Your doctor will discuss with you the possible risks and benefits of using Cefepime during breast-feeding.

Tell your doctor if you have or have had any medical conditions, including:

- kidney disease
- severe bowel conditions/disease
- frequent infections such as fever, severe chills, sore throat or mouth ulcers or lack of white blood cells (neutropoemia)
- a recent bone marrow transplant
- cancer of the blood
- low blood pressure
- if you have ever suffered diarrhoea as a result of taking medicine.

If you have not told your doctor about any of the above, tell them before you take/are given DBL™ Cefepime Powder for Injection.

Taking other medicines

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

Some medicines may interfere with DBL™ Cefepime Powder for Injection. These include:

- any other antibiotic
- fluid tablets (diuretics) such as Lasix, Midamor, or Moduretic

These medicines may be affected by DBL™ Cefepime Powder for Injection, or may affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Children

DBL™ Cefepime Powder for Injection may be given to infants (over 2 months old) and children; DBL™ Cefepime Powder for

Injection is not recommended if the infant is less than 2 months old.

How DBL™ Cefepime Powder for Injection is given

DBL™ Cefepime Powder for Injection can be given in two ways:

- as a slow injection into a vein
- as a deep injection into a large muscle

DBL™ Cefepime Powder for Injection must only be given by a doctor or nurse.

Your doctor will decide what dose and how long you will receive DBL™ Cefepime Powder for Injection.

This depends on your infection and other factors, such as your weight.

For most infections, it is usually given every 8 or 12 hours throughout the day.

Usually, it is given for 7 to 10 days, but sometimes only a single dose of DBL™ Cefepime Powder for Injection is required for the treatment and prevention of certain infections.

Follow all directions given to you by your doctor and pharmacist carefully.

The directions may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help.

If you take too much (overdose)

As DBL™ Cefepime Powder for Injection is given to you under the supervision of your doctor, it is very unlikely that you will receive too much. However, if you experience any severe side effects after being given DBL™ Cefepime Powder for Injection, tell your doctor immediately or go to Accident and Emergency at the nearest hospital.

You may need urgent medical attention.

In case of overdose, immediately contact the Poisons Information Centre for advice (telephone 13 11 26 in Australia, or call 0800 764 766 in New Zealand).

While you are using DBL™ Cefepime Powder for Injection

Things you must do

If the symptoms of your infection do not improve within a few days, or if they become worse, tell your doctor.

If you get severe diarrhoea tell your doctor, pharmacist or nurse immediately. Do this even if it occurs several weeks after DBL™ Cefepime Powder for Injection has been stopped.

Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care. Do not take any diarrhoea medicine without first checking with your doctor.

If you get a sore white mouth or tongue while taking or soon after stopping DBL™ Cefepime Powder for Injection, tell your doctor. Also tell your doctor if you get vaginal itching or discharge.

This may mean you have a fungal infection called thrush. Sometimes the use of DBL™ Cefepime Powder for Injection allows fungi to grow and the above symptoms to occur. DBL™ Cefepime Powder for Injection does not work against fungi.

If you become pregnant while you are on DBL™ Cefepime Powder for Injection tell your doctor immediately.

If you are about to start taking any new medicine, tell your doctor and pharmacist that you are taking DBL™ Cefepime Powder for Injection.

If you have to test your urine for sugar while you are using/being given DBL™ Cefepime Powder for Injection, make sure your doctor knows which type of test you use. DBL™ Cefepime Powder for Injection may affect the results of some of these tests.

If you have to have any blood tests tell your doctor you are taking/using/being given DBL™ Cefepime Powder for Injection. DBL™ Cefepime Powder for Injection may affect the results of some blood tests.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking DBL™ Cefepime Powder for Injection.

Things to be careful of

Be careful driving or operating machinery until you know how DBL™ Cefepime Powder for Injection affects you.

DBL™ Cefepime Powder for Injection generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, DBL™ Cefepime Powder for Injection may cause dizziness, drowsiness or tiredness in some people.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking DBL™ Cefepime Powder for Injection. DBL™ Cefepime Powder for Injection 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 treatment if you get some of the side effects.

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

Laboratory Tests:

DBL™ Cefepime Powder for Injection may cause adverse effects to the blood, liver or kidneys which are detected by laboratory testing. It may be necessary to monitor these effects by having your blood samples analysed regularly. Your doctor will advise if it is necessary for you to have these tests done.

While taking DBL™ Cefepime Powder for Injection

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

- oral thrush - white, furry, sore tongue and mouth
- vaginal thrush - sore and itchy vagina and/or discharge
- itching or burning while passing urine
- cough, sore throat, mouth ulcers
- swelling, pain and inflammation at the site of the injection
- any change to your bowel habits - diarrhoea or constipation
- pain in the gut, indigestion or upset stomach
- sweating, feeling unwell, fluid retention, headache weakness, numbness
- insomnia, anxiety, or nervousness

These side effects are usually mild.

Tell your doctor immediately if you notice any of the following:

- chest pain, increased heart beat, feeling faint,
- skin rash or itchiness, skin redness
- breathing difficulty or asthma
- chills
- dizziness
- confusion or hallucinations, twitching muscles, seizure

These are serious side effects. You may need urgent medical attention. Serious side effects are rare.

After finishing DBL™ Cefepime Powder for Injection

Tell your doctor immediately if you notice any of the following side effects, particularly if they occur several weeks after stopping treatment with DBL™ Cefepime Powder for Injection:

- severe abdominal cramps or stomach cramps
- watery and severe diarrhoea, which may also be bloody
- fever, in combination with one or both of the above

These are rare but serious side effects. You may have a serious condition affecting your bowel. Therefore, you may need urgent medical attention. However, this side effect is rare.

Do not take any diarrhoea medicine without first checking with your doctor.

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

Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using DBL™ Cefepime Powder for Injection

Storage

DBL™ Cefepime Powder for Injection will be stored in the pharmacy or on the ward.

The powder for injection is kept in a cool dry place where the temperature stays below 25°C.

Product description

What it looks like

DBL™ Cefepime Powder for Injection is a white to pale yellow powder.

Ingredients

Each vial of DBL™ Cefepime Powder for Injection contains as the active ingredient:

- Cefepime (as hydrochloride)

It also contains the following inactive ingredients:

- L-Arginine

DBL™ Cefepime Powder for Injection does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

Sponsor

DBL™ Cefepime Powder for Injection is supplied by:

Australian Sponsor:

Hospira Australia Pty Ltd
ABN 58 097 064 330
Level 3
500 Collins Street
Melbourne VIC 3000 Australia

New Zealand Sponsor:

Hospira NZ Limited
23 Haining Street
Te Aro
Wellington
New Zealand

DBL™ Cefepime Powder for Injection is available in the following strengths:

- 1g Cefepime/vial
AUST R 161397
- 2g Cefepime/vial
AUST R 161412

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