

OMEGAPHARM CEFEPIME FOR INJECTION 1 g and 2 g

Cefepime (as Cefepime hydrochloride)

Consumer Medicine Information

What is in this leaflet:

The medicine which your doctor has prescribed for you is called Omegapharm Cefepime for Injection. The information in this leaflet answers some questions you may have about Omegapharm Cefepime for Injection.

This leaflet does not contain all the information about Omegapharm Cefepime for Injection. Your doctor or pharmacist has been provided with full information, and can answer any questions you may have. Follow your doctor's advice, even if it differs from what is in this leaflet.

You should read this leaflet carefully before Omegapharm Cefepime for Injection is given to you. Keep this leaflet in a safe place, you may need to read it again.

What Omegapharm Cefepime for Injection is used for:

Omegapharm Cefepime for Injection contains cefepime which belongs to a group of antibiotics called cephalosporins. These antibiotics work by killing the bacteria that are causing the infection.

Omegapharm Cefepime 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). It may be given before surgery or if you have a lack of white blood cells with fever.

Omegapharm Cefepime 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), or in the skin; or in the blood; or if the child has a lack of white blood cells with fever.

There may be other reasons why your doctor has prescribed Omegapharm Cefepime for Injection. Ask your doctor why Omegapharm Cefepime for Injection has been prescribed for you.

Before you are given Omegapharm Cefepime for Injection:

When you must not be given Omegapharm Cefepime for Injection

You should not be given Omegapharm Cefepime for Injection if -

- you have an allergy to Omegapharm Cefepime for Injection, or to other cephalosporins or to any ingredient listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include skin rash, difficulty breathing or fever.
- you have had a serious reaction to penicillin.

Before you are given Omegapharm Cefepime for Injection:

Before you are given Omegapharm Cefepime for Injection your doctor must know -

- if you have ever had any type of allergic reaction to penicillin medicines
- if you have any allergies to other medicines or to any other substances such as foods, preservatives or dyes
- if you have ever had any other health problems or medical conditions such as -
 - kidney disease
 - severe bowel conditions or bowel disease
 - frequent infections such as fever, severe chills, sore throat or mouth ulcers or lack of white blood cells (neutropenia)
 - a recent bone marrow transplant
 - cancer of the blood
 - low blood pressure

- if you have ever suffered diarrhoea as a result of taking medicine.

Pregnancy and breast-feeding

Tell your doctor if:

- you are pregnant or intend to become pregnant
- breast-feeding or plan to breast-feed

Like most medicines Omegapharm Cefepime for Injection is not recommended for women who are pregnant or breast-feeding. However your doctor will discuss with you the possible risks and benefits of using Omegapharm Cefepime for Injection during pregnancy.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy or health food shop. Some medicines may interfere with Omegapharm Cefepime for Injection, these include -

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

These medicines may be affected by Omegapharm Cefepime for Injection, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Children

Omegapharm Cefepime for Injection may be given to infants (over 2 months old) and children; Omegapharm Cefepime for Injection is not recommended if the infant is less than 2 months old.

How Omegapharm Cefepime for Injection is given:

How much is given

Your doctor will decide what dose you will receive.

The usual adult dose is 1 gram given by injection every 12 hours (2 each day) for 7 to 10 days.

The dose of Omegapharm Cefepime for Injection for children aged 2 months to 12 years old will depend on the weight of the child, the severity of the infection and the medical condition of the child.

How it is given

Omegapharm Cefepime for Injection is given as a slow injection (or drip) directly into a vein or as a deep injection into a large muscle.

The injection will be given to you by a nurse or doctor, you will not be giving the injection to yourself.

Overdose

Usually you will be in hospital when receiving Omegapharm Cefepime for Injection. Your doctor has information on how to recognise and treat an overdose. Ask your doctor or nurse if you have any concerns when you are receiving Omegapharm Cefepime for Injection.

While you are being given Omegapharm Cefepime for Injection:

Things you must do

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

- If you get severe diarrhoea tell your doctor, pharmacist or nurse immediately even if it occurs several weeks after Omegapharm Cefepime 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 checking with your doctor first.
- If you get a sore white mouth or tongue while receiving or soon after stopping Omegapharm Cefepime 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 Omegapharm Cefepime for Injection allows fungi to grow and the symptoms described above to occur. Omegapharm Cefepime for Injection does not work against fungi.
- If you become pregnant while you are being given Omegapharm Cefepime for Injection tell your doctor.
- If you are about to start taking any new medicine, tell your doctor and pharmacist that you are receiving Omegapharm Cefepime for Injection.
- If you have your urine tested for sugar while you are receiving Omegapharm Cefepime for Injection, make sure your doctor knows which test is used. Omegapharm Cefepime for Injection may affect the results of some of these tests.
- Tell all the doctors, dentists and pharmacists who are treating you that you are taking Omegapharm Cefepime for Injection.

Things to be careful of

Be careful driving or operating machinery until you know how Omegapharm Cefepime for Injection affects you. Omegapharm Cefepime for Injection generally does not cause any problems with your ability to drive a car or operate machinery. However as with other medicines, Omegapharm Cefepime for Injection may cause dizziness, drowsiness or tiredness in some people.

Side effects:

It is important that you tell a nurse, doctor or pharmacist if you experience any problems when you are being treated with Omegapharm Cefepime for Injection.

Omegapharm Cefepime for Injection helps most people with infections, but it may cause some unwanted side effects in a few people. All medicines have side effects, some times they are serious, most of the time they are not. You may need special medical treatment if you get some of the side effects.

Infections:

If there are any germs present which are not sensitive to Omegapharm Cefepime for Injection, they may flourish during Omegapharm Cefepime for Injection therapy and cause other infections such as thrush.

Laboratory Tests:

Omegapharm Cefepime 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.

Call for a nurse or doctor immediately if you experience any of the following -

- chest pain, increased heart beat, feeling faint, breathing difficulty, chills, dizziness, asthma

- feel confused, suffer hallucinations, twitching muscles or experience a seizure

Tell your doctor if you notice any of the following -

- 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
- skin rash or itchiness, skin redness
- sweating, feeling unwell, fluid retention, headache, weakness, numbness
- insomnia, anxiety, nervousness, confusion

After treatment with Omegapharm Cefepime for Injection is finished

Tell your doctor immediately if you notice any of the following side effects, particularly if they occur several weeks after the treatment with Omegapharm Cefepime for Injection has stopped -

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

These are rare but serious side effects. You may have a serious condition affecting your bowel. Therefore you may need urgent medical attention. Although this side effect is rare, do not take diarrhoea medicine without first checking with your doctor.

The list above is not a complete list of ALL possible side effects. Your doctor can tell you more about the safety of Omegapharm Cefepime for Injection. Also, as with any medicine, there are some side effects which are not yet known. Ask your doctor if you have any questions.

Storage

Omegapharm Cefepime for Injection will be stored in the pharmacy or the Ward. The powder for injection is usually kept in a cool dry place where the temperature stays below 25°Celsius.

Protect from light.

Product description:

What Omegapharm Cefepime for Injection looks like

Omegapharm Cefepime for Injection is a white to pale yellow powder.

Ingredients

Each vial contains the active ingredient cefepime 1 g or 2 g (as cefepime hydrochloride).

The vials also contain the inactive ingredient arginine.

The contents of each vial are dissolved in sterile water, 5% glucose or saline for injection before the injection is given.

Sponsor:

Omegapharm Cefepime for Injection is distributed in Australia by:

Name and Address of the Sponsor

Omegapharm Pty Ltd
15A Leinster Street
Ormond
Victoria 3204
Australia

Omegapharm Cefepime for Injection

1 g (AUST R 156642)

Omegapharm Cefepime for Injection

2 g (AUST R 156641)

Date of Preparation

This leaflet was prepared in August
2010.

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