

CEFEPIME ALPHAPHARM

contains the active ingredient cefepime hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Cefepime Alphapharm. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

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.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Cefepime Alphapharm against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What Cefepime Alphapharm is used for

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

Cefepime Alphapharm 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.

Cefepime Alphapharm 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.

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.

Before you are given Cefepime Alphapharm

When you must not be given Cefepime Alphapharm

You should not be given Cefepime Alphapharm if you have an allergy to:

- you have an allergy to Cefepime Alphapharm, or to other cephalosporins or to any ingredient listed at the end of this leaflet.
- you have had a serious reaction to penicillin.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- fever
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Before you are given CEFEPIME ALPHAPHARM

Before you are given Cefepime Alphapharm 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 ulcer or lack of white blood cells.
 - 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
- you are breast-feeding or plan to breast-feed

Like most medicines Cefepime Alphapharm 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 Cefepime Alphapharm 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 Cefepime Alphapharm, these include:

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

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

Children

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

How to take CEFEPIME ALPHAPHARM

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 Cefepime Alphapharm 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

Cefepime Alphapharm 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 Cefepime Alphapharm. Your doctor has information on how to recognize and treat an overdose. Ask your doctor or nurse if you have any concerns when you are receiving Cefepime Alphapharm

While you are being given CEFEPIME ALPHAPHARM

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 Cefepime Alphapharm 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 Cefepime Alphapharm, 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 Cefepime Alphapharm allows fungi to grow and the symptoms described above to occur. Cefepime Alphapharm does not work against fungi.

- If you become pregnant while you are being given Cefepime Alphapharm tell your doctor.
- If you are about to start taking any new medicine, tell your doctor and pharmacist that you are receiving Cefepime Alphapharm.
- If you have your urine tested for sugar while you are receiving Cefepime Alphapharm, make sure your doctor knows which test is used. Cefepime Alphapharm may affect the results of some of these tests.
- Tell all the doctors, dentists and pharmacists who are treating you that you are receiving Cefepime Alphapharm.

Things to be careful of

Be careful driving or operating machinery until you know how Cefepime Alphapharm affects you. Cefepime Alphapharm generally does not cause any problems with your ability to drive a car or operate machinery. However as with other medicines, Cefepime Alphapharm 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 Cefepime Alphapharm.

Cefepime Alphapharm helps most people with infections, but it may cause some unwanted side effects in a few people. All medicines have side effects, sometimes 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 Cefepime Alphapharm, they may flourish

during Cefepime Alphapharm therapy and cause other infections such as thrush.

Laboratory Tests:

Cefepime Alphapharm 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 if you experience any of the following:

- Chest pain, increased heartbeat, feeling faint, breathing difficulty, chills, dizziness, asthma
- feel confused, suffer hallucinations, twitching muscles or experience a seizure

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

After treatment with Cefepime Alphapharm 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 Cefepime Alphapharm 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 Cefepime Alphapharm. Also, as with any medicine, there are some side effects which are not yet known. Ask your doctor if you have any questions.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor to answer any questions you may have.

Storage

Cefepime Alphapharm 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 degrees Celsius. Protect from light.

Product description

What it looks like

CEFEPIME ALPHAPHARM is a white to pale yellow colour.

Ingredients

Active ingredient per vial:

CEFEPIME ALPHAPHARM 1g - contains cefepime (as hydrochloride) 1g.

CEFEPIME ALPHAPHARM 2g - contains cefepime (as hydrochloride) 2g.

Inactive ingredients:

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

Supplier

CEFEPIME ALPHAPHARM is supplied in Australia by:

Alphapharm Pty Limited

Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
www.mylan.com.au

Australian Registration Numbers

CEFEPIME ALPHAPHARM 1g -
AUST R 161029

CEFEPIME ALPHAPHARM 2g -
AUST R 161030

This document was prepared in July 2019.

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