Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Cefepime Kabi. 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 being given Cefepime Kabi against the benefits this medicine is expected to have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What Cefepime Kabi is used for

Cefepime Kabi 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.

Cefepime Kabi 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. It will not work against infections caused by viruses such as colds or the flu.

Cefepime Kabi 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).

Cefepime Kabi 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.

Your doctor may have prescribed Cefepime Kabi for another reason. Ask your doctor if you have any questions about why Cefepime Kabi has been prescribed for you.

Before you are given Cefepime Kabi

When you must not be given it

You must not be given Cefepime Kabi if:

you have an allergy to Cefepime Kabi, 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, difficulty breathing, dizziness, flushing, sweating and swelling of the face, tongue or other parts of the body.

 you have had a serious allergic reaction to beta-lactam or penicillin antibiotics. Do not use Cefepime Kabi Powder for Injection if the packaging is torn or shows signs of tampering.

Before you are given it

Tell your doctor if you have any allergies to:

- · any antibiotic medicine
- · any other medicines
- any other substances such as foods, preservatives or dyes

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 (neutropoenia)
- · a recent bone marrow transplant
- · cancer of the blood
- · low blood pressure
- if you have ever suffered diarrhoea as a result of taking medicine.

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 Cefepime Kabi during pregnancy.

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

Your doctor will discuss with you the possible risks and benefits of using Cefepime Kabi during breast-feeding.

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 Cefepime Kabi. These include:-

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

These medicines may be affected by Cefepime Kabi 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.

Children

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

How Cefepime Kabi is given

Cefepime Kabi Powder for Injection can be given in two ways:

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

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

Your doctor will decide what dose and how long you will receive Cefepime Kabi 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 Cefepime Kabi Powder for Injection is required for the treatment and prevention of certain infections.

Overdose

Usually you will be in hospital when receiving Cefepime Kabi Powder 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 receiving Cefepime Kabi Powder for Injection.

While you are using Cefepime Kabi

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 Cefepime Kabi 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 Cefepime Kabi 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 Cefepime Kabi Powder for Injection allows fungi to grow and the above symptoms to occur. Cefepime Kabi Powder for Injection does not work against fungi.

If you become pregnant while you are on Cefepime Kabi 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 being given Cefepime Kabi Powder for Injection.

If you have to test your urine for sugar while you are being given Cefepime Kabi Powder for Injection, make sure your doctor knows which type of test you use. Cefepime Kabi 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 being given Cefepime Kabi Powder for Injection.

Cefepime Kabi 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 being given Cefepime Kabi Powder for Injection.

Things to be careful of

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

Cefepime Kabi 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, Cefepime Kabi Powder 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 Cefepime Kabi Powder for Injection.

Cefepime Kabi Powder for Injection 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.

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

- insomnia, anxiety, nervousness, confusion
- passing little or no urine, painful urination, drowsiness, nausea, vomiting, poor appetite, headache, weakness, fever, numbness, fluid retention
- severe abdominal cramps or stomach cramps, watery and severe diarrhoea, which may also be bloody, fever with one or both of the above symptoms
- · fever, chills, sore throat, mouth ulcers

The most common side-effects are listed below;

- · rash, itchy red skin
- nausea, vomiting, diarrhoea, constipation
- · headache, fever
- oral thrush white, furry, sore tongue and mouth; vaginal thrush - sore and itchy vagina and/or discharge
- pain or swelling at injection site

Tell your doctor immediately, or go to accident and emergency at your nearest hospital if you notice any of the following;

- signs of a sudden life-threatening allergic reactions such as; chills, fever, fast heartbeat, wheezing or coughing, difficulty breathing, dizziness, flushing, sweating and swelling of the face, tongue or other parts of the body
- Signs of altered mental state such as;confusion, hallucinations, lethargy, tremor, seizures or muscle twitching

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

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

Tell your doctor if you notice any other effects.

After treatment with Cefepime Kabi Powder for Injection is finished

Tell your doctor, nurse or pharmacist if you notice any of the following side effects, particularly if they occur several weeks after stopping treatment with Cefepime Kabi Powder for Injection;

- 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. You may need urgent medical attention or hospitalisation.

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

Storage

Cefepime Kabi Powder for Injection will be stored in the pharmacy or the ward appropriately. The powder for injection is kept in the original container and stored in the dry state in a cool dry place where the temperature stays below 25°C.

Product description

What Cefepime Kabi Powder for Injection looks like

Cefepime Kabi is a white to pale yellow powder.

Ingredients

Each vial contains the active ingredient cefepime hydrochloride monohydrate 1g or 2σ

The vials also contain the inactive ingredient L-arginine.

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

Supplier

Cefepime Kabi Powder for Injection is supplied in Australia by:

Fresenius Kabi Australia Pty Limited Level 2, 2 Woodland Way Mount Kuring-gai NSW 2080

Australia

Telephone: (02) 9391 5555

Cefepime Kabi Powder for Injection is supplied in New Zealand by:

Fresenius Kabi New Zealand Limited 60 Pavilion Drive

Airport Oaks, Auckland 2022 New Zealand

Freecall: 0800 144 892

Australian Registration Numbers:

1 g vial - AUST R 227966 2 g vial- AUST R 227965

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