

## CEFEPIME-AFT

Cefepime (as hydrochloride monohydrate) 500 mg, 1g and 2 g powder for injection

### Consumer Medicine Information

#### What is in this leaflet

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

This leaflet does not contain all the information about Cefepime-AFT. 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 Cefepime-AFT is given to you. Keep this leaflet in a safe place; you may need to read it again.

#### What Cefepime-AFT is used for

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

Cefepime-AFT 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-AFT 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 Cefepime-AFT. Ask your doctor why Cefepime-AFT has been prescribed for you.

#### Before you are given Cefepime-AFT

##### When you must not be given Cefepime-AFT

You should not be given Cefepime-AFT if -

- You have an allergy to Cefepime-AFT, or to other cephalosporins or to any ingredient listed at the end of this leaflet. Symptoms of a severe allergic reaction may include chills, fever, fast heart beat, wheezing or coughing, difficulty breathing, dizziness, flushing, sweating and swelling of the face, tongue or other parts of the body.
- You have had a serious reaction to cephalosporin, beta-lactam or penicillin antibiotics.

##### Before you are given Cefepime-AFT

Before you are given Cefepime-AFT your doctor must know -

- if you have ever had any type of allergic reaction to antibiotic 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 Cefepime-AFT 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-AFT 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-AFT, these include -

- any other antibiotic
- Fluid tablets (diuretics) such as Lasix (frusemide), Midamor (amiloride), or Moduretic (amiloride and hydrochlorothiazide).

These medicines may be affected by Cefepime-AFT, 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-AFT may be given to infants (over 2 months old) and children; Cefepime-AFT is not recommended if the infant is less than 2 months old.

#### How Cefepime-AFT is given

##### How much is given

Your doctor will decide what dose you will receive. This dose will be based on your size, as well as the severity and location of your infection.

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-AFT 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-AFT 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.

Laboratory Tests: Cefepime-AFT 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.

##### Overdose

Usually you will be in hospital when receiving Cefepime-AFT. 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 Cefepime-AFT.

#### While you are being given Cefepime-AFT

##### 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-AFT 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-AFT, 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-AFT allows fungi to grow and the symptoms described above to occur. Cefepime-AFT does not work against fungi.
- If you become pregnant while you are being given Cefepime-AFT tell your doctor.
- If you are about to start taking any new medicine, tell your doctor and pharmacist that you are receiving Cefepime-AFT.
- If you have your urine tested for sugar while you are receiving Cefepime-AFT, make sure your doctor knows which test is used. Cefepime-AFT may affect the results of some of these tests.
- Tell all the doctors, dentists and pharmacists who are treating you that you are taking Cefepime-AFT.

##### Things to be careful of

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

#### 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-AFT.

Cefepime-AFT 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

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

- Signs of a sudden life-threatening allergic reaction such as fast heart beat, feeling faint, wheezing or coughing, difficulty breathing, chills, fever, 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, twitching muscles or experience a seizure

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

**Tell your doctor or nurse if you notice any of the following -**

- insomnia, anxiety, nervousness, confusion
- itching or burning while passing urine, passing little or no urine, drowsiness, nausea, vomiting, poor appetite, headache, weakness, fever, numbness, fluid retention
- severe abdominal or stomach cramps, watery and severe diarrhoea (which may be bloody), fever with one or both of the above symptoms
- Fevers, chills, sore throat, mouth ulcer

The most common side-effects are:

- oral thrush - white, furry, sore tongue and mouth
- vaginal thrush - sore and itchy vagina and/or discharge
- swelling, pain and inflammation at the site of the injection
- skin rash or itchiness, skin redness
- nausea, vomiting, diarrhoea, constipation
- Headache, fever

**After treatment with Cefepime-AFT 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-AFT has stopped -**

- severe abdominal 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-AFT. Also, as with any medicine, there are some side effects which are not yet known. Ask your doctor if you have any questions.

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

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## Product description

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### *What Cefepime-AFT looks like*

Cefepime-AFT is a white to pale yellow powder.

### *Ingredients*

Each vial contains cefepime hydrochloride monohydrate equivalent to cefepime 500 mg, 1 g or 2 g.

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.

### *Sponsor*

AFT Pharmaceuticals Pty. Ltd  
P.O. Box 748 , North Ryde, NSW 1670  
113 Wicks Road, North Ryde, NSW 2113

### **Australian Registration Numbers:**

500 mg vial AUST R 196281

1 g vial AUST R 196279

2 g vial AUST R 196280

This leaflet was prepared on 24 August 2015

Please note that knowledge about the safety of all medicines may change over time. You should, therefore, see your doctor if you have any questions about Cefepime-AFT at any time.

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## Storage

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Cefepime-AFT will be stored in the pharmacy or the Ward. The powder for