

Cefepime-AFT

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I given Cefepime-AFT

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

For more information, see Section [1. Why am I given Cefepime-AFT?](#) in the full CMI.

2. What should I know before I am given Cefepime-AFT

Do not use if you have ever had an allergic reaction to Cefepime-AFT or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I am given Cefepime-AFT?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Cefepime-AFT and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How am I given Cefepime-AFT?

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. More instructions can be found in Section [4. How do I am I given Cefepime-AFT?](#) in the full CMI.

5. What should I know while I am given-Cefepime-AFT?

Things you should do	<ul style="list-style-type: none">• Tell all the doctors, dentists and pharmacists who are treating you that you are taking Cefepime-AFT.• 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.• 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.• If you become pregnant while you are being given Cefepime-AFT tell your doctor.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how Cefepime-AFT affects you.
Looking after your medicine	<ul style="list-style-type: none">• Cefepime-AFT will be stored in the hospital pharmacy or in the ward. It will be kept in original packaging below 25 °C, protected from light.

For more information, see Section [5. What should I know while using Cefepime-AFT?](#) in the full CMI.

6. Are there any side effects?

Like all medicines, Cefepime-AFT can cause side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some side effects.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Cefepime-AFT

Active ingredient: Cefepime (as hydrochloride monohydrate)

Consumer Medicine Information (CMI)

This leaflet provides important information about using Cefepime-AFT. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Cefepime-AFT.**

Where to find information in this leaflet:

- [1. Why am I given Cefepime-AFT?](#)
- [2. What should I know before I am given Cefepime-AFT?](#)
- [3. What if I am taking other medicines?](#)
- [4. How am I given Cefepime-AFT?](#)
- [5. What should I know while I am given Cefepime-AFT?](#)
- [6. Are there any side effects?](#)
- [7. Product details.](#)

1. Why am I given Cefepime-AFT?

Cefepime-AFT contains the active ingredient cefepime hydrochloride monohydrate 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.

2. What should I know before I am given Cefepime-AFT?

Warnings

When you must not be given Cefepime-AFT

- 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 heartbeat, 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.

Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have ever had any type of allergic reaction to antibiotic medicines
- take any medicines for any other condition
- have any allergies to other medicines or to any other substances such as foods, preservatives or dyes
- have ever suffered diarrhoea as a result of taking medicine
- 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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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.

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.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or

supplements that you buy without a prescription from your pharmacy, supermarket 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affects Cefepime-AFT.

4. How am I given Cefepime-AFT?

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.

If you use are given too much

Usually, you will be in hospital when receiving Cefepime-AFT. 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-AFT. If you think that you have been given too much Cefepime-AFT, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while I am given Cefepime-AFT?

Things you should 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.

Driving or using machines

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.

Looking after your medicine

Cefepime-AFT will be stored in the hospital pharmacy or in the ward. It will be kept in original packaging below 25 °C, protected from light.

Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Sleep and mood effect:</p> <ul style="list-style-type: none"> • insomnia, • anxiety, • nervousness • confusion <p>Urinary symptoms:</p> <ul style="list-style-type: none"> • itching or burning while passing urine. • passing little or no urine <p>Gastrointestinal symptoms:</p> <ul style="list-style-type: none"> • nausea • vomiting • constipation • poor appetite • diarrhoea <p>Brain and nervous system related:</p> <ul style="list-style-type: none"> • weakness • numbness • drowsiness • headaches <p>Injection site reactions:</p> <ul style="list-style-type: none"> • swelling at the site of injection • pain and inflammation at the site of injection <p>Skin related:</p> <ul style="list-style-type: none"> • skin rash or itchiness • skin redness <p>Flu like symptoms:</p> <ul style="list-style-type: none"> • fever • chills • sore throat <p>Body as a whole:</p> <ul style="list-style-type: none"> • fluid retention • mouth ulcer • oral thrush - white, furry, sore tongue and mouth • vaginal thrush - sore and itchy vagina and/or discharge 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Brain and nervous system related:</p> <ul style="list-style-type: none"> • signs of altered mental state such as confusion, hallucinations, lethargy, tremor, twitching muscles or experience a seizure <p>Allergy related:</p> <ul style="list-style-type: none"> • signs of a sudden life-threatening allergic reaction such as fast heartbeat, feeling faint, wheezing or coughing, difficulty breathing, chills, fever, dizziness, flushing, sweating and swelling of the face, tongue or other parts of the body 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

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.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

6. Product details

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

What Cefepime-AFT contains

Active ingredient (main ingredient)	Cefepime hydrochloride monohydrate
Other ingredients (inactive ingredients)	L-arginine

Do not take this medicine if you are allergic to any of these ingredients.

What Cefepime-AFT looks like

Cefepime-AFT is a white to pale yellow powder. It is reconstituted before being injected.

Cefepime-AFT 500 mg (Aust R 196281)

Cefepime-AFT 1 g (Aust R 196279)

Cefepime-AFT 2 g (Aust R 196280)

Who distributes Cefepime-AFT

AFT Pharmaceuticals Pty Ltd

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North Ryde

NSW 2113

Australia

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This leaflet was prepared in March 2024