WHAT IS IN THIS LEAFLET
This leaflet answers some common questions about Cefepime Sandoz.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

What Cefepime Sandoz is used for
Cefepime Sandoz contains the active ingredient cefepime.

Cefepime belongs to a group of antibiotics called cephalosporins. It works by killing the bacteria that are causing the infection.

This medicine is an injectable antibiotic used to treat serious infections in adults caused by bacteria in the:

- lung (pneumonia and bronchitis)
- kidney and bladder (urinary tract infections)
- skin
- abdomen (peritonitis and biliary tract infections)
- womb or vagina
- blood (septicaemia).

It may also be given in children over 2 months of age caused by bacteria in the:

- lung (pneumonia)
- kidney and bladder (urinary tract infections)
- skin
- blood (septicaemia).

It may also be given if the child has a lack of white blood cells with fever.

Cefepime Sandoz is also used for serious infections in children over 2 months of age caused by bacteria in the:

- lung (pneumonia)
- kidney and bladder (urinary tract infections)
- skin
- blood (septicaemia).

It may also be given if the child has a lack of white blood cells with fever.

Ask your doctor or pharmacist if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

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

BEFORE YOU ARE GIVEN CEFEPIME SANDOZ

When you must not be given it
Do not receive this medicine if you have an allergy to:

- Cefepime, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product Description
- beta-lactam or penicillin antibiotics
- any other similar medicines such as cephalosporin antibiotics and penicillin.

Some of the symptoms of an allergic reaction may include:

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

Do not receive this medicine after the expiry date printed on the vial or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, it may not work as well.

If you are not sure whether you should start receiving this medicine, talk to your doctor.

Tell your doctor if you have been pregnant while you are being given Cefepime Sandoz.

Tell your doctor if you have any of the following medical conditions:

- 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.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you are given Cefepime Sandoz.

Taking other medicines
Tell your doctor or pharmacist if you are taking any other medicines, including any that get you without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Cefepime Sandoz may interfere with each other. These include:

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

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

Your doctor and pharmacist have more information on medicines to be careful with or avoid while receiving and after receiving this medicine.

How it is given
Cefepime Sandoz is given as a slow injection (or drip) 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.

If you are given too much (overdose)
As Cefepime Sandoz is given to you under the supervision of your doctor, it is very unlikely that you will receive too much. However, if you experience any unexpected or worrying side effects after being given Cefepime Sandoz, telephone your doctor or the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764766) for advice, or go to Accident and Emergency at the nearest hospital.

You may need urgent medical attention.

WHILE YOU ARE BEING GIVEN CEFEPIME SANDOZ

Things you must do
If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being given Cefepime Sandoz.

If you become pregnant while you are being given this medicine, tell your doctor immediately.

If you are about to have any urine tests for sugar while being given Cefepime Sandoz, make sure your doctor knows which test is used.

It may interfere with the results of some tests.

Tell any other doctors, dentists, and pharmacists who treat you that you have been given this medicine.

Tell your doctor, nurse or pharmacist if the following occurs:

- If the symptoms of your infection do not improve within a few days, or if they become worse.
- If you get severe diarrhoea, even if it occurs several weeks after Cefepime Sandoz has been stopped. Diarrhoea may mean you have a serious condition affecting your bowel.
- You may need urgent medical care. Do not take diarrhoea medicine without checking with your doctor first.
- If you get a sore white mouth or tongue, or vaginal itching or discharge while receiving or soon after receiving Cefepime Sandoz.

This may mean that you have a fungal infection called thrush.

Things to be careful of
Be careful driving or operating machinery until you know how Cefepime Sandoz affects you.

This medicine generally does not cause any problems with your ability to drive a car or operate machinery. However, as with other medicines, Cefepime Sandoz may cause dizziness, tiredness, or drowsiness, in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.
SIDE EFFECTS

Tell your doctor, nurse or pharmacist as soon as possible if you experience any problems while being given Cefepime Sandoz.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

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

Tell your doctor, nurse or pharmacist to answer any questions you may have.

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

• white, furry, sore tongue and mouth (oral thrush)
• sore and itchy vagina and/or discharge (vaginal thrush)
• itching or burning while passing urine
• swelling, pain and inflammation at the site of 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.

The above list includes serious side effects that may require medical attention.

If any of the following happen, tell your doctor or nurse immediately:

• chest pain, increased heartbeat, feeling faint, breathing difficulty, chills, dizziness, asthma.
• Feel confused, suffer hallucinations, twitching muscles or experience a seizure.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor, nurse or pharmacist if you notice anything else that is making you feel unwell.

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

After treatment with Cefepime Sandoz is finished

Tell your doctor, nurse or pharmacist immediately if you notice any of the following side effects, particularly if they occur several weeks after the treatment with Cefepime Sandoz has finished:

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

The above list includes very serious side effects. You may have a serious condition affecting your bowel. You may need urgent medical attention or hospitalisation. These side effects are very rare. Although this side effect is rare, do not take diarrhoea medicine without first checking with your doctor.

Storage

Cefepime Sandoz will be stored in the pharmacy or on the ward. The powder for injection is kept in a cool dry place, where the temperature stays below 25°C.

Disposal

The hospital staff will dispose of any unused Cefepime Sandoz.

PRODUCT DESCRIPTION

What it looks like

Cefepime Sandoz comes in 2 types of vials:

• Cefepime Sandoz 1g - 20mL clear glass vial with rubber stopper (latex free) and flip-off aluminium crimp and a white plastic cap, containing a white to pale yellow sterile powder. Available in packs of 1 or 10 vials.
• Cefepime Sandoz 2g - 50mL clear glass bottle with rubber stopper (latex free) and flip-off aluminium crimp and a white plastic cap, containing a white to pale yellow sterile powder. Available in packs of 1 or 10 vials.

Cefepime Sandoz powder for injection is mixed with solution before being given as a injection or being transferred into an infusion bag/glass bottle ready for your infusion in the ward.

Ingredients

Active ingredients:

• Cefepime Sandoz 1g - 1g cefepime (as hydrochloride)
• Cefepime Sandoz 2g - 2g cefepime (as hydrochloride)

Inactive ingredients:

• L-arginine

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Your doctor, nurse or pharmacist can inform you what other ingredients are in your injection, infusion bag or glass bottle.

Supplier

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Cefepime Sandoz 2g powder for injection: AUST R 171734