PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

CEFTAZIDIME 500 mg FRESENIUS Powder for solution for Injection

CEFTAZIDIME 1 000 mg FRESENIUS Powder for solution for Injection

CEFTAZIDIME 2 000 mg FRESENIUS Powder for solution for Injection or Infusion

Ceftazidime

Sugar free

Read all of this leaflet carefully before you are given CEFTAZIDIME FRESENIUS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.

What is in this leaflet

1. What FRESENIUS CEFTAZIDIME is and what it is used for

CEFTAZIDIME FRESENIUS is an antibiotic. It belongs to a group of antibiotics called “Cephalosporins”. CEFTAZIDIME FRESENIUS kills bacteria and can be used to treat some infections.

CEFTAZIDIME FRESENIUS only works against some types of bacteria. This means that it is only suitable for treating some types of infection.

CEFTAZIDIME FRESENIUS is used to treat serious infections, such as blood poisoning (sepsis), abdominal infections (peritonitis), or infected burns. It is also used to treat some infections of the:

- Chest
- Ear, nose and throat
- Bladder and kidneys (urinary system)
- Skin and layers beneath the skin
- Stomach and bowel (the gut, digestive system).

2. What you need to know before you are given CEFTAZIDIME FRESENIUS

CEFTAZIDIME FRESENIUS should not be administered to you:

- If you are hypersensitive (allergic) to ceftazidime or any of the other ingredients of CEFTAZIDIME FRESENIUS (listed in section 6).
- If you are hypersensitive (allergic) to any cephalosporin type of antibiotic (like ceftazidime) or beta-lactam antibiotics (like avibactam).
- If you have ever had a severe allergic reaction to other antibiotics (e.g. penicillin, monobactam or carbapenem).

If you are not sure about anything, ask your doctor or pharmacist.

Warnings and precautions

Take special care with CEFTAZIDIME FRESENIUS

Tell your doctor or healthcare provider before being given the injection:

- If you have ever had an allergic reaction (even if only a skin rash) to any other group of antibiotics – such as penicillins or carbapenems.

- If you develop diarrhoea during or after treatment with CEFTAZIDIME FRESENIUS. If this happens, do not take medicines that stop or slow bowel movement - rather speak to your healthcare provider.
- If you had a bowel problem called colitis, or any serious problem affecting your gut.
- If you have kidney problems. Your doctor may give you a lower dose to make sure you do not get too much medicine. This could have an effect on the brain and can cause symptoms such as fits.
- If you have liver problems.
- If you are on a low salt diet.

If any of these apply to you, your doctor may want to change your treatment or give you special advice.

Tell your doctor that you are receiving CEFTAZIDIME FRESENIUS if you are going to have any tests. This is because you may get an abnormal result with a test called “DAGT” or “Coombs”. This test looks for antibodies that fight against your red blood cells.

CEFTAZIDIME FRESENIUS can also affect the results of some urine tests for sugar. Tell the person taking the sample that you have been given CEFTAZIDIME FRESENIUS.

Other medicines and CEFTAZIDIME FRESENIUS

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor or pharmacist if you are taking:

- Any other antibiotics, particularly aminoglycosides (such as gentamycin), tetracyclines, sulphonamides or chloramphenicol
- “Water tablets” (diuretics), such as furosemide
- Probenecid (a medicine used to treat gout).

CEFTAZIDIME FRESENIUS with food and drink

You can eat and drink as usual when having this medicine.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, nurse, pharmacist or other healthcare provider for advice before receiving CEFTAZIDIME FRESENIUS.

Pregnancy

Tell your doctor if you are pregnant or think you might be pregnant. Safety in pregnancy has not been established. CEFTAZIDIME FRESENIUS should not be given to you during pregnancy unless clearly necessary.

Breastfeeding

Do not use CEFTAZIDIME FRESENIUS if you are breastfeeding, because CEFTAZIDIME FRESENIUS can pass into breast milk.

Fertility

No information is available in humans.

Driving and using machines

You may get dizzy or have fits (convulsions) when given CEFTAZIDIME FRESENIUS.

It is not always possible to predict to what extent CEFTAZIDIME FRESENIUS may interfere with your daily activities. You should not engage in the above activities until you are aware of the measure to which CEFTAZIDIME FRESENIUS affects you.

CEFTAZIDIME FRESENIUS contains sodium

Tell your doctor if you are on a sodium-controlled diet before receiving CEFTAZIDIME FRESENIUS.

The sodium content of CEFTAZIDIME FRESENIUS (26 mg sodium for CEFTAZIDIME 500 mg FRESENIUS, 52 mg sodium for CEFTAZIDIME 1 000 mg FRESENIUS and 104 mg sodium for CEFTAZIDIME 2 000 mg FRESENIUS) should be considered if you are on a controlled sodium diet.

3. How to receive CEFTAZIDIME FRESENIUS

Do not share medicines prescribed for you with any other person.

You will not be expected to give yourself CEFTAZIDIME FRESENIUS. It will be given to you by a person who is qualified to do so.

CEFTAZIDIME FRESENIUS is given:

- By slow injection into a vein (intravenous) or
- By infusion (a drip) into a vein (intravenous infusion) or
- By deep injection into a large muscle (intramuscular), such as the upper buttock or thigh.

The dose depends on the infection you have and how bad it is. The dose also depends on your age, your weight, and how well your kidneys are working. Your doctor will explain this to you.

Your doctor will tell you how long your treatment with CEFTAZIDIME FRESENIUS will last. Do not stop treatment early.

If you have the impression that the effect of CEFTAZIDIME FRESENIUS is too strong or too weak, tell your doctor or pharmacist.

If you receive more FRESENIUS CEFTAZIDIME than you should

Since a healthcare provider will administer CEFTAZIDIME FRESENIUS, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use FRESENIUS CEFTAZIDIME

Since a healthcare provider will administer CEFTAZIDIME FRESENIUS, it is unlikely that the dose will be missed.

4. Possible side effects

CEFTAZIDIME FRESENIUS can have side effects.

Not all side effects reported for CEFTAZIDIME FRESENIUS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving CEFTAZIDIME FRESENIUS**,** consult your healthcare provider for advice.

If any of the following happens, stop receiving CEFTAZIDIME FRESENIUS and tell your doctor immediately

- Severe allergic reaction (called anaphylaxis) associated with sudden wheezing or breathlessness, swelling of face, hands, feet, ankles, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Raised and itchy rash. The skin rash may blister and look like small targets (central dark spot surrounded by a paler area, with a dark ring around the edge).
- A widespread rash with blisters and peeling skin. (These may be signs of Stevens-Johnson syndrome or toxic epidermal necrolysis).
- A severe rash, which may be accompanied by fever, fatigue, swelling of the face or lymph glands, increase of eosinophils (type of white blood cells), effects on liver, kidney or lung (a reaction called DRESS).
- fainting (loss of consciousness).

These are all very serious side effects. If you have them, you may have had a serious reaction to CEFTAZIDIME FRESENIUS. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately if you notice any of the following

- Loose stools/diarrhoea, nausea (feeling like throwing up), vomiting, inflammation of the colon, stools that contain blood or mucous.
- Yellowing of the skin or the whites of the eyes, also called jaundice.
- Tremors, fits and, in some cases coma. These symptoms have occurred in people when the dose they are given is too high, particularly in people with kidney disease.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Candida (yeast) infection, vaginal inflammation, oral thrush.

- Abnormal result with a blood test called “DAGT” - this test looks for antibodies that fight against your red blood cells.
- Higher than normal level of eosinophils (a type of white blood cell). This condition could indicate an infection and is shown in a blood test.
- Too many platelets (thrombocytosis), shown in your blood tests. Too many platelets can lead to certain conditions, including stroke, heart attack.
- An abnormally low level of platelets in the blood (thrombocytopenia), shown in your blood tests. This may cause delayed blood coagulation, bleeding complications.
- Headache, dizziness.
- Stomach pain.
- Increase in the amount of some enzymes produced by your liver – shown in blood tests. These results indicate if your liver is working well.
- High levels of lactate dehydrogenase (LDH) (shown in blood test). When your LDH rises, it means that tissues may have been damaged or are diseased.
- Rash, itching, skin eruptions, allergic inflammation of the skin, hives, swelling.
- Redness, pain, swelling (inflammation) where CEFTAZIDIME FRESENIUS was given into a vein.
- Fever.

Less frequent side effects:

- Too few, to a serious low count of white blood cells (neutropenia, leukopenia), high lymphocyte count (a type of white blood cell). This may be due to an infection and is shown in blood tests.
- Burning, numbness, pins and needles sensation (paraesthesia).
- Bad taste in your mouth.
- Swelling in a part of the kidney that causes a reduction in its normal working function (inflammation in the kidneys).

- Increase in the level of some types of substances in your blood (called creatinine or urea), shown in your blood tests. These results indicate if your kidneys are working well.

Side effects with unknown frequency:

- An acute condition (agranulocytosis) causing a severe and dangerous lowered white blood cell count, shown in your blood tests.
- Anaemia due to haemolysis (the abnormal breakdown of red blood cells), shown in your blood tests.
- Seizures, particularly if you have severe renal impairment.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of CEFTAZIDIME FRESENIUS.

Patients are asked to report any suspected adverse drug reactions to their healthcare provider or Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-kabi.com and to the relevant medicine's regulatory authority in the country where the product is marketed.

5. How to store CEFTAZIDIME FRESENIUS

Store all medicines out of the reach of children.

Do not use CEFTAZIDIME FRESENIUS after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.

Store at or below 25 °C. Protect from light.

Once CEFTAZIDIME FRESENIUS powder is made into a solution for injection, it is stable for 6 hours at 25 ºC and 12 hours at 5 ºC.

Any remaining reconstituted solution must be discarded after use.

The solution should not be given if it is cloudy; it should be completely clear.

Do not dispose of unused medicines in drains or sewerage systems (e.g. toilets). Your doctor or nurse will dispose of any medicine that is no longer required.

6. Contents of the pack and other information

What CEFTAZIDIME FRESENIUS contains

- The active substance is ceftazidime.

  CEFTAZIDIME 500 mg FRESENIUS: Each vial contains 500 mg ceftazidime.

  CEFTAZIDIME 1 000 mg FRESENIUS: Each vial contains 1 000 mg ceftazidime.

  CEFTAZIDIME 2 000 mg FRESENIUS: Each infusion bottle contains 2 000 mg ceftazidime.

- The other ingredients are:

  Anhydrous sodium carbonate.

What CEFTAZIDIME FRESENIUS looks like and contents of the pack

Vial/infusion bottle containing a white to yellowish powder for solution for injection or infusion.

CEFTAZIDIME 500 mg FRESENIUS:

10 mL type II, clear colourless glass vial closed with red and dark grey rubber stoppers and green aluminium/plastic caps, in packs of 1 and 10.

CEFTAZIDIME 1 000 mg FRESENIUS:

10 mL type II, clear colourless glass vials closed with red and dark grey rubber stoppers and blue aluminium/plastic caps, in packs of 1 and 10.

CEFTAZIDIME 2 000 mg FRESENIUS:

50 mL type II, clear colourless glass infusion bottles closed with red and dark grey rubber stoppers and red aluminium/plastic caps, in packs of 1 and 10.

Packed in 1’s or 10’s in a cardboard carton.

Holder of Certificate of Registration

FRESENIUS KABI SOUTH AFRICA (PTY) LIMITED

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CEFTAZIDIME 2 000 mg FRESENIUS: 43/20.1.1/0555

Access to the corresponding information

The professional information will be printed and packed with the product.