PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

ZAVICEFTA® 2 g/0,5 g powder for concentrate for solution for infusion

Ceftazidime and avibactam

Sugar free

Read all of this leaflet carefully before you or your child are given ZAVICEFTA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ZAVICEFTA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What ZAVICEFTA is and what it is used for
2. What you need to know before you or your child are given ZAVICEFTA
3. How ZAVICEFTA will be administered to you or your child
4. Possible side effects
5. How to store ZAVICEFTA
6. Contents of the pack and other information

1. What ZAVICEFTA is and what it is used for

ZAVICEFTA is an antibiotic medicine that works by killing certain types of bacteria which cause serious infections.

ZAVICEFTA is used for treatment of adults and paediatric patients 3 months of age and over who are hospitalised for the following:

- complicated infections of the abdomen (stomach and gut)

- complicated infections of the bladder or kidneys called ‘urinary tract infections’
- infection of the lungs that have developed while in hospital or while on a lung ventilator
- infections caused by bacteria that other antibiotics may not be able to kill

ZAVICEFTA is used in adults to treat infection of the blood associated with infections of the abdomen, urinary tract, or pneumonia.

2. What you need to know before you or your child are given ZAVICEFTA

ZAVICEFTA should not be administered to you or your child:

- if you are hypersensitive (allergic) to ceftazidime, avibactam or any of the other ingredients of ZAVICEFTA (listed in section 6)
- if you are hypersensitive (allergic) to other cephalosporin antibiotics (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)

Warnings and precautions

Tell your doctor or health care provider before you or your child are given the injection:

- if you have ever had any allergic reaction (even if only a skin rash) to other groups of antibiotics – such as penicillins or carbapenems
- if you develop diarrhoea during or after treatment with ZAVICEFTA. If this happens, do not take medicines that stop or slow bowel movement - rather speak to your health care provider
- 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 are on a sodium-controlled diet

Tell your doctor that you are taking ZAVICEFTA 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.

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

Children and adolescents

ZAVICEFTA should not be used in paediatric patients under 3 months of age. This is because it is not known if ZAVICEFTA is safe to use in this age group.

Other medicines and ZAVICEFTA

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

You should inform your doctor if you are taking or have taken any of the following medicines:

- aminoglycosides (a type of antibiotic)
- furosemide (a diuretic or “water tablet”)
- chloramphenicol (an antibiotic)
- probenecid (a medicine used to treat gout)

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before receiving ZAVICEFTA.

ZAVICEFTA should not be given to you during pregnancy unless clearly necessary.

You should not breastfeed your baby during your treatment with ZAVICEFTA.

Driving and using machines

ZAVICEFTA may make you feel dizzy and could influence your ability to drive and use machines.

It is not always possible to predict to what extent ZAVICEFTA may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ZAVICEFTA affects them.

ZAVICEFTA contains sodium

If you are on a sodium-controlled diet, tell your health care provider before receiving ZAVICEFTA.

This medicine contains approximately 146 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 7,3 % of the recommended maximum daily dietary intake of sodium for an adult.

Talk to your doctor or pharmacist if you need 3 or more vials daily for a prolonged period, especially if you have been advised to have a low salt (sodium) diet.

3. How ZAVICEFTA will be administered to you or your child

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

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

The recommended dose for adults is one vial (2 g of ceftazidime and 0,5 g of avibactam), every 8 hours.

The dose for paediatric patients 3 months of age and over will be calculated by the health care provider based on the weight and age of the child.

It is given as a drip into a vein – this will take about 2 hours.

A course of treatment usually lasts from 5 to 14 days, depending on the type of infection you have and how you respond to treatment.

If you have kidney problems, your doctor may lower your dose. This is because ZAVICEFTA is removed from your body by the kidneys.

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

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

If you or your child receive more ZAVICEFTA than you should

Since a health care provider will administer ZAVICEFTA, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you or your child miss~~ed~~ a dose of ZAVICEFTA

Since a health care provider will administer ZAVICEFTA, it is unlikely that the dose will be missed.

4. Possible side effects

ZAVICEFTA can have side effects.

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

Tell your doctor immediately if you notice any of the following:

- severe allergic reactions – signs include sudden swelling of your lips, face, throat or tongue, a severe rash or other severe skin reactions, difficulty swallowing or breathing
- diarrhoea that keeps getting worse or does not go away, or stools that contain blood or mucous
- sudden onset of a severe rash or blistering or peeling skin, possibly accompanied by a high fever or joint pain (these may be signs of more serious medical conditions such as toxic epidermal necrolysis, Stevens-Johnson syndrome, erythema multiforme or a condition known as DRESS, Drug Reaction with Eosinophilia and Systemic Symptoms)
- yellowing of the skin and eyes, also called jaundice

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

Other side effects reported with ZAVICEFTA include:

Frequently reported side effects

- abnormal result with a test called ”DAGT” - this test looks for antibodies that fight against your red blood cells
- fungal infections, including those of the mouth and vagina
- change in the number of some types of blood cells (called eosinophils and thrombocytes) - shown in blood tests
- headache
- feeling dizzy
- diarrhoea
- stomach pain
- feeling like throwing up (nausea)
- vomiting
- increase in the amount of some enzymes produced by your liver – shown in blood tests
- raised itchy skin rash (‘hives’)
- itchiness
- redness, pain or swelling where ZAVICEFTA was given into a vein

- fever

Less frequently reported side effects

- increase in the number of a type of blood cell (called lymphocytes) – shown in blood tests
- decrease in the type of white blood cells used to fight infection – shown in blood tests
- decrease in the number of red blood cells – shown in blood tests
- burning, numbness, tingling or prickling
- bad taste in your mouth
- increase in the level of some types of substances in your blood (called creatinine or urea) – shown in blood tests. These show how well your kidneys are working
- swelling in a part of the kidney that causes a reduction in its normal working function

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 **"6.04 Adverse Drug Reaction Reporting Form"**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of ZAVICEFTA.

5. How to store ZAVICEFTA

Store all medicines out of reach of children.

Store at or below 30 °C.

Store in the original package in order to protect from light.

Your health care provider or hospital will ensure that ZAVICEFTA is stored and disposed of correctly.

6. Contents of the pack and other information

What ZAVICEFTA contains

The active ingredients are ceftazidime and avibactam.

Each vial contains ceftazidime pentahydrate equivalent to 2 g ceftazidime and avibactam sodium equivalent to 0,5 g avibactam. After reconstitution, 1 mL of solution contains 167,3 mg of ceftazidime and 41,8 mg of avibactam.

The other ingredient is sodium carbonate.

What ZAVICEFTA looks like and contents of the pack

A white to pale yellow sterile powder.

The reconstituted solution is a clear and colourless to yellow solution free from visible particulate matter.

ZAVICEFTA is sterile, pyrogen-free and free from visible particles.

ZAVICEFTA is available in a 20 mL clear glass vial (Type 1) closed with a grey rubber (bromobutyl) stopper and aluminium flip-off overseal cap. The flip-off cap is light blue in colour.

ZAVICEFTA is supplied in packs of 10 vials. Vials are packed in an outer cardboard carton.

Holder of Certificate of Registration

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This leaflet was revised in

22 January 2024

Registration number

53/20.1.1/0060