Your doctor is the best resource for medical advice and information. The health information contained herein is provided for educational / awareness purposes only and is not intended to replace discussions with a medical practitioner and/or medical advice or be construed as a promotional information.

Package Leaflet: Information for the user
Ceftazidime Pentahydrate and Avibactam Sodium
2 g/0.5 g Powder for Concentrate for Solution for Infusion
ZAVICEFTA®

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Zavicefta (Ceftazidime Pentahydrate and Avibactam Sodium) is and what it is used for
2. What you need to know before you take Zavicefta (Ceftazidime Pentahydrate and Avibactam Sodium)
3. How to take Zavicefta (Ceftazidime Pentahydrate and Avibactam Sodium)
4. Possible side effects
5. How to store Zavicefta (Ceftazidime Pentahydrate and Avibactam Sodium)
6. Contents of the pack and other information

1. What Zavicefta (Ceftazidime Pentahydrate and Avibactam Sodium) is and what it is used for

What Zavicefta (Ceftazidime Pentahydrate and Avibactam Sodium) is

Zavicefta (Ceftazidime Pentahydrate and Avibactam Sodium) is an antibiotic medicine that contains two active substances ceftazidime and avibactam.

- Ceftazidime belongs to the group of antibiotics called “cephalosporins”. It can kill many types of bacteria.
- Avibactam is a “beta-lactamase inhibitor” that helps ceftazidime kill some bacteria that it cannot kill on its own.

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What Zavicefta (Ceftazidime Pentahydrate and Avibactam Sodium) is used for

Zavicefta (Ceftazidime Pentahydrate and Avibactam Sodium) is used in adults to treat:

- Infections of the stomach and gut (abdomen) (Complicated intra-abdominal infection (cIAI))
- Infections of the bladder or kidneys called "urinary tract infections" (Complicated urinary tract infection (cUTI), including pyelonephritis)
- An infection of the lungs called "pneumonia" (Hospital-acquired pneumonia (HAP), including ventilator associated pneumonia (VAP) with susceptible gram negative microorganisms)

Treatment of patients with bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above.

Consideration should be given to official guidance on the appropriate use of antibacterial agents.

How Zavicefta (Ceftazidime Pentahydrate and Avibactam Sodium) works

Zavicefta (Ceftazidime Pentahydrate and Avibactam Sodium) works by killing certain types of bacteria, which can cause serious infections.

2. What you need to know before you take Zavicefta (Ceftazidime Pentahydrate and Avibactam Sodium)

Do not use Zavicefta (Ceftazidime Pentahydrate and Avibactam Sodium) if:

- You are allergic to ceftazidime, avibactam or any of the other ingredients of this medicine (listed in section 6)
- You are allergic to other cephalosporin antibiotics
- You have ever had a severe allergic reaction to other antibiotics belonging to the penicillins, monobactams or carbapenem groups

Do not use Zavicefta (Ceftazidime Pentahydrate and Avibactam Sodium) if any of the above apply to you. If you are not sure, talk to your doctor before using Zavicefta (Ceftazidime Pentahydrate and Avibactam Sodium).

Warnings and precautions

- *Hypersensitivity reactions*: Serious and occasionally fatal hypersensitivity reactions are possible In case of hypersensitivity reactions, treatment with Ceftazidime Pentahydrate and Avibactam Sodium must be discontinued immediately and adequate emergency measures must be initiated.

- serious skin reactions including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS), acute generalised exanthematous pustulosis (AGEP) have been reported in association with ceftazidime treatment. Seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

  Inform your doctor if you have ever had any allergic reaction (even if only a skin rash) to other antibiotics belonging to the penicillin, monobactams or carbapenem groups

- *Clostridium difficile-associated diarrhoea:* Mild to life-threatening Clostridium difficile-associated diarrhoea has been reported with ceftazidime/avibactam. Inform your doctor if you experience diarrhoea during or subsequent to the administration of Ceftazidime Pentahydrate and Avibactam Sodium.
- *If you have kidney problems:* Your doctor may give you a lower dose to make sure you don't get too much medicine. This could cause symptoms such as fits, encephalopathy and coma. Using this medicine with high doses of cephalosporins, nephrotoxic medicinal products such as aminoglycosides or potent diuretics (e.g. furosemide) may adversely affect renal function.

If any of the above apply to you (or you are not sure), talk to your doctor before using Zavicefta (Ceftazidime Pentahydrate and Avibactam Sodium).

Lab tests

Tell your doctor that you are taking Zavicefta (Ceftazidime Pentahydrate and Avibactam Sodium) 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

Other medicines and Zavicefta (Ceftazidime Pentahydrate and Avibactam Sodium)

Tell your doctor if you are using, have recently used or might use any other medicines.

Talk to your doctor before using Zavicefta (Ceftazidime Pentahydrate and Avibactam Sodium) if you are taking any of the following medicines:

- An antibiotic called chloramphenicol
- A type of antibiotic called an aminoglycoside – such as gentamicin, tobramycin
- A water tablet called furosemide
- A medicine for gout called probenecid

Tell your doctor before using Zavicefta (Ceftazidime Pentahydrate and Avibactam Sodium) if any of the above apply to you.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine.

Driving and using machines

Zavicefta (Ceftazidime Pentahydrate and Avibactam Sodium) may make you feel dizzy. This may affect you being able to drive and use machines.

Zavicefta contains sodium

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 for 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 to take Zavicefta (Ceftazidime Pentahydrate and Avibactam Sodium)

Zavicefta (Ceftazidime Pentahydrate and Avibactam Sodium) will be given to you by a doctor or a nurse.

How much to use

The recommended dose is one vial (2 g of ceftazidime and 0.5 g of avibactam), every 8 hours.

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

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

People with kidney problems

If you have kidney problems your doctor may lower your dose. This is because Zavicefta (Ceftazidime Pentahydrate and Avibactam Sodium) is removed from your body by the kidneys.

If you use more Zavicefta (Ceftazidime Pentahydrate and Avibactam Sodium) than you should

Zavicefta (Ceftazidime Pentahydrate and Avibactam Sodium) will be given to you by a doctor or a nurse, so it is unlikely you will be given the wrong dose. However, if you have side effects or think you have been given too much Zavicefta (Ceftazidime Pentahydrate and Avibactam Sodium), tell your doctor straight away. If you have too much Zavicefta (Ceftazidime Pentahydrate and Avibactam Sodium) it could have an effect on the brain and cause fits or coma.

If you miss a dose of Zavicefta (Ceftazidime Pentahydrate and Avibactam Sodium)

If you think you have missed a dose, tell your doctor straight away.

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Serious side effects
Tell your doctor straight away if you notice any of the following serious side effects - you may need urgent medical treatment:

- reddish patches on the trunk, the patches are target-like macules or circular, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis).
- widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).

- a red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalised exanthematous pustulosis).
- 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, or sudden chest pain (which may be a sign of Kounis syndrome). These reactions may be life-threatening.
- diarrhoea that keeps getting worse or does not go away, or stools that contains blood or mucus – this may happen during or after treatment is stopped with Zavicefta. If this happens do not take medicines that stop or slow bowel movement.

Tell your doctor straight away if you notice any of the serious side effects above.

Other side effects
Tell your doctor or nurse if you notice any of the following side effects:

Very common: (may affect more than 1 in 10 people)

Abnormal result with a test called "DAGT" or "Coombs". This test looks for antibodies that fight against your red blood cells.

Common: (may affect up to 1 in 10 people)

- 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
- Feeling sick (nausea) or being sick (vomiting)
- Stomach pain
- Diarrhoea
- 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 (Ceftazidime Pentahydrate and Avibactam Sodium) was given into a vein
- Fever

Uncommon: (may affect up to 1 in 100 people)

- Increase in the number of a type of blood cell (called "lymphocytes") – shown in blood tests
- Decrease in the number of some types of blood cells (called "leucocytes") – shown in blood tests
- Tingling or numbness
- Bad taste in your mouth
- An increase in the level of some types of substances in your blood (called "creatinine" and "urea"). These show how well your kidneys are working.

Very rare: (may affect up to 1 in 10,000 people)

- Swelling in a part of the kidney that causes a reduction in its normal working function

Not known: (frequency cannot be estimated from the available data)

- Significant decrease in the type of white blood cells used to fight infection – shown in blood tests
- Decrease in the number of red blood cells (haemolytic anaemia) – shown in blood tests
- Severe allergic reaction
- Yellowing of the whites of the eyes or skin
- 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, a condition known as DRESS, Drug Reaction with Eosinophilia and Systemic Symptoms or acute generalised exanthematous pustulosis (AGEP))
- Swelling under the skin, particularly lips and around the eyes

Tell your doctor if you notice any of the side effects listed above.

5. How to store Zavicefta (Ceftazidime Pentahydrate and Avibactam Sodium)

Store below 30°C.
Store in the original package in order to protect from light.
Keep this medicine out of the sight and reach of children.

6. Contents of the pack and other information

What Zavicefta (Ceftazidime Pentahydrate and Avibactam Sodium) contains

- The active substances are ceftazidime and avibactam. Each vial contains ceftazidime pentahydrate equivalent to 2 g ceftazidime and avibactam sodium equivalent to 0.5 g avibactam.
- The other ingredient is sodium carbonate (anhydrous).

What Zavicefta (Ceftazidime Pentahydrate and Avibactam Sodium) looks like and contents of the pack

Zavicefta (Ceftazidime Pentahydrate and Avibactam Sodium) is a white to yellow powder for concentrate for solution for infusion in a vial.

20 mL glass vial (Type 1) closed with a rubber (bromobutyl) stopper and aluminium seal with flip-off cap.

It is available in packs containing 10 vials.

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