Zavicefta® 2000/500

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.

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details.

1. Why am I being treated with Zavicefta?

Zavicefta contains the active ingredients, ceftazidime and avibactam. It is used to treat serious infections of the tissues and organs within the stomach, urinary tract or kidney or certain serious lung infections.

For more information, see Section 1. Why am I being treated with Zavicefta? in the full CMI.

2. What should I know before treatment with Zavicefta?

Do not start treatment if you/your child have ever had an allergic reaction to Zavicefta/ceftazidime/avibactam, other antibiotics that are the same type, or any of the

ingredients listed at the end of the CMI including sodium carbonate.

Tell the doctor if you/your child have had any allergic reaction to any antibiotic, have other medical conditions, are on a controlled sodium diet, take any other medicines or if you are pregnant, plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before treatment with Zavicefta? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Zavicefta and affect how it works.

More instructions can be found in in Section 3. What if I am taking other medicines? in the full CMI.

4. How is Zavicefta given?

The doctor will decide how much Zavicefta is needed. It will depend on the type of infection, age and bodyweight (for children) and if you/your child have kidney problems.

More instructions can be found in Section 4. How is Zavicefta given? in the full CMI.

5. What should I know during treatment with Zavicefta?

Things you should do	• Tell your doctor if you/ your child have kidney problems, anaemia, are on a controlled sodium diet, had severe diarrhoea after taking any antibiotics or if you are pregnant, plan to become pregnant or are breastfeeding. • For more information on "Things you should do" can be found in Section 6 in the full CMI.
Things you should not do	• You/your child should not be treated with Zavicefta if you/your child have had a serious allergy to penicillin or the same type of antibiotics as Zavicefta.
Driving or using machines	• Zavicefta may affect your ability to drive a car or operate machinery.

Looking after your medicine	• Store in original carton at below 30°C until ready for use.

For more information, see Section 5. What should I know during treatment with Zavicefta? in the full CMI.

6. Are there any side effects?

Side effects may include swelling of the face, lips, mouth or throat, difficulty swallowing or breathing; shortness of breath or breathing difficulties; nausea or vomiting; changes in taste or a metallic taste; stomach or abdominal pain; severe diarrhoea or stools that contains blood or mucus; severe skin rash; weight gain; increased urine volume; night urination; numbness or a tingling sensation; redness, pain or swelling at the injection site or vein; headaches; dizziness; fever; itchy skin; hives/skin rash; white, furry layer on the tongue; unusual vaginal discharge; yellowing of skin and eyes (jaundice),.problems with your liver or kidneys, certain blood cells or the way your blood clots.

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

▼ This medicine is subject to additional monitoring in Australia. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problem.

ZAVICEFTA®

Active ingredient(s): *ceftazidime/avibactam*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

1. Why am I being treated with Zavicefta?
2. What should I know before treatment with Zavicefta?
3. What if I am taking other medicines?
4. How is Zavicefta given to you?
5. What should I know while being treated with Zavicefta?
6. Are there any side effects?
7. Product details

1. Why am I being treated with Zavicefta?

Zavicefta contains the active ingredients ceftazidime and avibactam**.** Zavicefta is an antibiotic used in adults and children from 3 months to treat serious infections of the tissues and organs within the stomach, urinary tract or kidney infections and in adults to treat certain lung infections.

2. What should I know before treatment with Zavicefta?

Do not use Zavicefta if you/your child are:

- allergic to Zavicefta/ceftazidime/avibactam or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- allergic to or have previously had a severe allergic reaction to penicillin or the same type of antibiotic as Zavicefta. Your doctor will know which antibiotics are the same type as Zavicefta.

Check with your doctor if you/your child:

- have kidney problems
- anaemia
- are on a controlled sodium diet
- have had severe diarrhoea after taking any antibiotics
- are taking medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for 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.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you/your child 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 and Zavicefta may interfere with each other. These include:

- probenecid, a medicine used to prevent gout and gouty arthritis
- a type of antibiotic called aminoglycosides, such as gentamicin and tobramycin
- a type of antibiotic called cephalosporins, such as cefazolin and ceftazidime
- chloramphenicol, a medicine used to treat eye infections
- medicines used to pass urine, such as frusemide

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Zavicefta.

4. How is Zavicefta given?

How much will be given

The doctor will decide what dose of Zavicefta is needed depending on certain factors such as the type of infection, age and body weight (for children) and if you/ your child have kidney problems.

How long will Zavicefta need to be given?

Treatment is usually given every day for 5 days to up to 14 days. The doctor will decide how many days you will need treatment with Zavicefta.

If too much Zavicefta is given

If you think that you/your child have been given too much Zavicefta, 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 during treatment with Zavicefta?

Things you should do

If you/your child are about to have any blood tests, tell the doctor or nurse that you/your child were recently treated with Zavicefta.

Call your doctor straight away if you/your child:

- get severe diarrhoea. Do this even if it occurs several weeks after Zavicefta has been stopped.

Remind any doctor, nurse, dentist or pharmacist you see that you are using Zavicefta.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Zavicefta affects you.

Zavicefta may affect your ability to drive a car or operate machinery.

Drinking alcohol

No information available.

Looking after your medicine

Zavicefta should be stored in the original carton below 30°C.

If you are keeping this medicine at home, store it in a cool dry place away from moisture, heat or sunlight. For example, do not store it in the bathroom, near a sink or in the car or on windowsills.

Keep it where young children cannot reach it.

When to discard your medicine

Discard any medicine that has passed the expiry date.

This medicine should only be used on one patient and any unused medicine should be discarded.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

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

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

Side effects	What to do
• Stomach pain • Diarrhoea • Nausea or vomiting • Changes in taste or a metallic taste in the mouth • Itchy skin • Skin rash or hives. • Dizziness • Headache • Fever • White, furry layer on the tongue • Unusual vaginal discharge • Redness, pain or swelling where injection was given into a vein • Problems with your liver or kidneys* • Problems with certain blood cells or the way your blood clots.* *These side effects may show up when you have a blood test.	**Speak to your doctor if you have any of these side effects and they worry you.**

Side effects	What to do
Side effects	**What to do**
• Swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing • Shortness of breath or breathing difficulties • Abdominal pain • Diarrhoea that keeps getting worse or does not go away, or stools that contains blood or mucus. This may occur even after treatment • Rash or hives with unusual weight gain, increased urine volume and night urination • Changes to urine volume. • Numbness or a tingling sensation • Severe skin reactions such as painful red areas, large blisters, peeling of your skin, and bleeding in the lips,	**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.**

Side effects	What to do
eyes, mouth, nose and genitals • Swelling of the limbs, face, lips, mouth or throat • Yellowing of the skin and eyes (jaundice).	

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

Other side effects not listed here may occur in some people.

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.

7. Product details

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

What Zavicefta contains

Active ingredients	Ceftazidime and avibactam
Other ingredients **(inactive ingredients)**	Sodium carbonate

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

What Zavicefta looks like

Zavicefta is a white to yellow powder, which will be dissolved to a clear and colourless to yellow solution before it is given to you.

Australian Registration Number: AUST R 301205.

Who distributes Zavicefta

Pfizer Australia Pty Ltd

Sydney NSW.

Toll Free Number: 1800 675 229.

www.pfizermedicalinformation.com.au.

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