

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### **Ceftazidime Venus Pharma 1 g powder for solution for injection/infusion Ceftazidime Venus Pharma 2 g powder for solution for injection/infusion ceftazidime**

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What Ceftazidime Venus Pharma is and what it is used for
2. What you need to know before you use Ceftazidime Venus Pharma
3. How to use Ceftazidime Venus Pharma
4. Possible side effects
5. How to store Ceftazidime Venus Pharma
6. Contents of the pack and other information

#### **1. What Ceftazidime Venus Pharma is and what it is used for**

Ceftazidime is an antibiotic used in adults and children (including newborn babies). It works by killing bacteria that cause infections. It belongs to a group of medicines called cephalosporins.

#### **Ceftazidime Venus Pharma is used to treat severe bacterial infections of:**

- the lungs or chest
- the lungs and bronchi in patients suffering from cystic fibrosis
- the brain (meningitis)
- the ear
- the urinary tract
- the skin and soft tissues
- the abdomen and abdominal wall (peritonitis)
- the bones and joints.

Ceftazidime Venus Pharma can also be used:

- to prevent infections during prostate surgery in men
- to treat patients with low white blood cell counts (neutropenia) who have a fever due to a bacterial infection.

## 2. What you need to know before you use Ceftazidime Venus Pharma

### Do not use Ceftazidime Venus Pharma:

- if you are allergic to ceftazidime or any of the other ingredients of this medicine (listed in section 6).
- if you have had a severe allergic reaction to any other antibiotic (penicillins, monobactams and carbapenems) as you may also be allergic to Ceftazidime.

→ **Tell your doctor before** you start on Ceftazidime if you think that this applies to you. You must not be given Ceftazidime.

### Warnings and precautions

You must look out for certain symptoms such as allergic reactions, nervous system disorders and gastrointestinal disorders such as diarrhoea while you are being given Ceftazidime. This will reduce the risk of possible problems. See ('Conditions you need to look out for') in section 4. If you have had an allergic reaction to other antibiotics you may also be allergic to Ceftazidime.

### If you need a blood or urine test

Ceftazidime can affect the results of urine tests for sugar and a blood test known as the Coombs test. If you are having tests:

→ **Tell the person taking the sample** that you have been given Ceftazidime.

### Other medicines and Ceftazidime Venus Pharma

Tell your doctor if you are taking any other medicines, if you've started taking any recently or you start taking new ones. This includes medicines you can obtain without a prescription.

You shouldn't be given Ceftazidime without talking to your doctor if you are also taking:

- an antibiotic called chloramphenicol
- a type of antibiotic called aminoglycosides e.g. gentamicin, tobramycin
- water tablets called furosemide

→ **Tell your doctor** if this applies to you.

### Pregnancy, breast-feeding and fertility

Ask your doctor for advice before you are given Ceftazidime:

- If you are pregnant, think you might be pregnant or are planning to become pregnant
- If you are breast-feeding

Your doctor will consider the benefit of treating you with Ceftazidime against the risk to your baby.

### Driving and using machines

Ceftazidime can cause side effects that affect your ability to drive, such as dizziness. Don't drive or use machines unless you are sure you're not affected.

### **Ceftazidime Venus Pharma contains sodium**

Ceftazidime Venus Pharma 1 g contains 52 mg of sodium per dose. This is equivalent to 2.6 % of the recommended maximum daily dietary intake of sodium for an adult.

Ceftazidime Venus Pharma 2 g contains 104 mg of sodium per dose. This is equivalent to 5.2 % of the recommended maximum daily dietary intake of sodium for an adult.

### **3. How to use Ceftazidime Venus Pharma**

**Ceftazidime is usually given by a doctor or nurse.** It can be given as a **drip** (intravenous infusion) or as an **injection** directly into a vein or into a muscle.

Ceftazidime is made up by the doctor, pharmacist or nurse using water for injections or a suitable infusion fluid.

#### **The recommended dose**

The correct dose of Ceftazidime for you will be decided by your doctor and depends on: the severity and type of infection; whether you are on any other antibiotics; your weight and age; how well your kidneys are working.

#### **Newborn babies (0-2 months)**

**For every 1 kg the baby weighs,** they'll be given 25 to 60 mg Ceftazidime per day divided in two doses.

#### **Babies (over 2 months) and children** who weigh less than 40 kg

**For every 1 kg the baby or child weighs,** they'll be given 100 to 150 mg of Ceftazidime per day divided in three doses. Maximum 6 g per day.

#### **Adults and adolescents** who weigh 40 kg or more

1 to 2 g of Ceftazidime three times daily. Maximum of 9 g per day.

#### **Patients over 65**

The daily dose should not normally exceed 3 g per day, especially if you are over 80 years of age.

#### **Patients with kidney problems**

You may be given a different dose to the usual dose. The doctor or nurse will decide how much Ceftazidime you will need, depending on the severity of the kidney disease. Your doctor will check you closely and you may have more regular kidney function tests.

#### **If you are given more Ceftazidime Venus Pharma than you should**

If you accidentally use more than your prescribed dose, contact your doctor or nearest hospital straight away.

### **If you forget to use Ceftazidime Venus Pharma**

However, if it is almost time for your next injection, skip the missed injection. Don't take a double dose (two injections at the same time) to make up for a missed dose.

### **Don't stop taking Ceftazidime Venus Pharma**

Don't stop taking Ceftazidime unless your doctor tells you to. If you have any further questions on the use of this medicine ask your doctor or nurse.

## **4. Possible Side Effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

### **Conditions you need to look out for**

The following serious side effects have occurred in a small number of people but their exact frequency is unknown:

- **severe allergic reaction.** Signs include **raised and itchy rash, swelling**, sometimes of the face or mouth causing **difficulty in breathing**.
- **Skin rash**, which may **blister**, and looks 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).
- **Nervous system disorders:** tremors, fits and, in some cases coma. These have occurred in people when the dose they are given is too high, particularly in people with kidney disease.
- There have been rare reports of severe hypersensitivity reactions with 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).

→ **Contact a doctor or nurse immediately if you get any of these symptoms.**

### **Common side effects**

These may affect **up to 1 in 10** people:

- Diarrhoea
- swelling and redness along a vein
- red raised skin rash which may be itchiness
- pain, burning, swelling or inflammation at the injection site.

→ **Tell your doctor** if any of these are troubling you.

Common side effects that may show up in blood tests:

- an increase in a type of white blood cell (eosinophilia)
- an increase in the number of cells that help the blood to clot

- an increase in liver enzymes.

### **Uncommon side effects**

These may affect **up to 1 in 100** people:

- inflammation of the gut which can cause pain, or diarrhoea which may contain blood
- thrush (fungal infections in the mouth or vagina)
- headache
- dizziness
- stomach ache
- feeling sick or being sick
- fever and chills.

→ **Tell your doctor** if you get any of these.

Uncommon side effects that may show up in blood tests:

- a decrease in the number of white blood cells•
- a decrease in the number of blood platelets (cells that help the blood to clot)
- an increase in the level of urea, urea nitrogen or serum creatinine in the blood.

### **Very rare side effects**

These may affect up to **1 in 10,000** people:

- inflammation or failure of the kidneys

### **Other side effects**

Other side effects have occurred in a small number of people but their exact frequency is unknown:

- inflammation or failure of the kidneys
- pins and needles
- unpleasant taste in the mouth
- yellowing of the whites of the eyes or skin.

Other side effects that may show up in blood tests:

- red blood cells destroyed too quickly
- an increase in a certain type of white blood cells
- severe decrease in the number of white blood cells.

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Ceftazidime Venus Pharma**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the vial and carton after EXP. The expiry date refers to the last day of that month.

This medical product does not require any special storage condition.

Keep vials in the outer carton to protect from light.

Reconstituted and diluted solution: The doctor, pharmacist or nurse will make up your medicine in Water for Injections or compatible fluids. Once made up, this medicine should be used within 6 days if stored in refrigerator (at 2 to 8°C) or within 9 hours if stored at room temperature (below 25°C).

Do not throw away any medicines via wastewater or household waste. Your doctor or nurse will throw away any medicine that is no longer required. This will help protect the environment.

## **6. Contents of the pack and other information**

### **What Ceftazidime Venus Pharma contains**

Ceftazidime Venus Pharma is available in the following strengths: 1 g and 2 g. The active substance 1 g and 2 g of ceftazidime (present as ceftazidime pentahydrate).

The only other ingredient is sodium carbonate (anhydrous sterile).

See section 2 for further important information about sodium, one of the ingredients of Ceftazidime Venus Pharma.

### **What Ceftazidime Venus Pharma looks like and contents of the pack**

Ceftazidime Venus Pharma 1 g powder for solution for injection/infusion is a sterile white to pale yellow powder packaged in 10 ml clear glass vials with a 20 mm grey butyl rubber plug and a 20 mm flip-off aluminium seal.

Ceftazidime Venus Pharma 2 g powder for solution for injection/infusion is a sterile white to pale yellow powder packaged in 20 ml clear glass vials with a 20 mm grey butyl rubber plug and a 20 mm flip-off aluminium seal.

Available in packs of 1, 5 or 10 vials.

Not all pack sizes may be marketed.

Your doctor, pharmacist or nurse will make the injection or infusion up with Water for Injections or a suitable infusion fluid.

### **Marketing Authorization Holder and Manufacturer**

Venus Pharma GmbH  
Am-Bahnhof 1-3,

59368, Werne,  
Germany

**This leaflet was last revised in May 2021.**

**The following information is intended for healthcare professionals only:  
Ceftazidime Venus Pharma 1 g powder for solution for injection/infusion  
Ceftazidime Venus Pharma 2 g powder for solution for injection/infusion  
ceftazidime**

**Please refer to the Summary of Product Characteristics for further information**

**Shelf Life**

2 years.

**After reconstitution:**

Chemical and physical in-use stability has been demonstrated for 6 days at 2 to 8°C and 9 hours at 25°C in Water for Injections or compatible fluids listed below.

From a microbiological point of view, the reconstituted solution should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless reconstitution has taken place in controlled and validated aseptic conditions.

**After dilution:**

Chemical and physical in-use stability has been demonstrated for 6 days at 2 to 8°C and 9 hours at 25°C in Water for Injections or compatible fluids listed below.

From a microbiological point of view, the reconstituted and diluted solution should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless reconstitution has taken place in controlled and validated aseptic conditions

**Special precautions for storage**

This medical product does not require any special storage condition.

Keep vials in the outer carton to protect from light.

Special precautions for disposal and other handling.

All sizes of vials of Ceftazidime Venus Pharma are supplied under reduced pressure. As the product dissolves, carbon dioxide is released and a positive pressure develops. Small bubbles of carbon dioxide in the constituted solution may be ignored.

Instructions for constitution See Table 1 and Table 2 for addition volumes and solution concentrations, which may be useful when fractional doses are required.



Table 1: Powder for Solution for Injection

Presentation		Amount of diluent to be added (ml)	Approximate concentration (mg/ml)
1 g			
	Intramuscular	3 ml	260
	Intravenous bolus	10 ml	90
2 g			
	Intravenous bolus	10 ml	170

Note: •The resulting volume of the solution of ceftazidime in reconstitution medium is increased due to the displacement factor of the drug product resulting in the listed concentrations in mg/ml presented in the above table.

Table 2: Powder for Solution for Infusion

Presentation		Amount of diluent to be added (ml)	Approximate concentration (mg/ml)
1 g			
	Intravenous infusion	50 ml*	20
2 g			
	Intravenous infusion	50 ml*	40

Note: The resulting volume of the solution of ceftazidime in reconstitution medium is increased due to the displacement factor of the drug product resulting in the listed concentrations in mg/ml presented in the above table.

Solution is clear with the defined concentration, diluents and storage conditions used.

Ceftazidime at concentrations between 1 mg/ml and 40 mg/ml is compatible with:

- sodium chloride 9 mg/ml (0.9%) solution for injection
- M/6 sodium lactate injection
- 5% dextrose injection
- 0.9% sodium chloride and 5% dextrose injection
- 10% dextrose Injection

Ceftazidime at concentrations detailed in Table 1 may be constituted for intramuscular use with 0.5% or 1% Lidocaine Hydrochloride Injection.

### **1 g and 2 g powder for solution for injection/infusion.:**

Preparation of solutions for iv infusion from ceftazidime injection in standard vial presentation (mini-bag or burette-type set):

Prepare using a total of 50 ml (for 1 g and 2 g vials) and 75 ml (for 3 g vials) of compatible diluents (listed above), added in TWO stages as below.

1. Introduce the syringe needle through the vial closure and inject 10 ml of diluent for the 1 g and 2 g vials.
2. Withdraw the needle and shake the vial to give a clear solution.

3. Do not insert a gas relief needle until the product has dissolved. Insert a gas relief needle through the vial closure to relieve the internal pressure.
4. Transfer the reconstituted solution to final delivery vehicle (e.g. mini-bag or burette-type set) making up a total volume of at least 50 ml (75 ml for the 3 g vial), and administer by intravenous infusion over 15 to 30 min.

Note: To preserve product sterility, it is important that the gas relief needle is not inserted through the vial closure before the product has dissolved.

Any residual antibiotic solution should be discarded.

For single use only.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

**This leaflet was last revised in May 2021.**