Ceftazidime 3 g

Powder for solution for injection or infusion

PACKAGE LEAFLET: INFORMATION FOR THE USER

Ceftazidime 3 g, Powder for solution for injection or 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.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. What Ceftazidime is and what it is used for

Ceftazidime contains the active substance Ceftazidime.
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 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 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 are given Ceftazidime

You must not be given Ceftazidime
- **if you are allergic** *(hypersensitive)* to **ceftazidime** or any 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 then.

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 (see section 4). This will reduce the risk of possible problems. 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 test for sugar and a blood test known as the *Coombs test*.
Other medicines and Ceftazidime
Tell your doctor if you are taking, have recently taken or might take any other medicines.
You shouldn't be given Ceftazidime without talking to your doctor if you are also taking:
- an antibiotic called *chloramphenicol*
- a type antibiotic called *aminoglycosides e.g., gentamicin, tobramycin*
- water tablets called *furosemide*

Pregnancy, breast-feeding and fertility
Tell your doctor before you are given Ceftazidime:
- If you are pregnant, think you might be pregnant or are planning to have a baby
- If you are breastfeeding

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 contains sodium
You need to take this into account if you are on a controlled sodium diet.
3 g: This medicinal product contains 153.6 mg (6.68 mmol) of sodium per dose.

3. How Ceftazidime is given

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 reconstituted by the doctor, pharmacist or nurse using water for injections or a suitable infusion fluid.
The usual 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.

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THE FOLLOWING INFORMATION IS INTENDED FOR HEALTHCARE PROFESSIONALS ONLY:

Routes of administration:
Only for 1 g, Powder for solution for injection or infusion:
Intravenous use,
Intramuscular use (in exceptional clinical situations)

Only for 2 g and 3 g, Powder for solution for injection or infusion:
Intravenous use

Method of administration:
Ceftazidime may be given intravenously by slow bolus injection over a few minutes.

Ceftazidime 1 g Powder for solution for injection or infusion may be given by deep intramuscular injection into a large muscle mass, such as the upper outer quadrant of the gluteus maximum or lateral part of the thigh. The intramuscular method of administration is reserved to exceptional clinical situations and should undergo a risk-benefit assessment.
Ceftazidime 1 g, 2 g and 3 g Powder for solution for injection or infusion may be given intravenously by infusion over 15-30 minutes.

Incompatibilities:
Ceftazidime should not be mixed with solutions with a pH above 7.5 for example sodium bicarbonate solution for injection. Ceftazidime and aminoglycosides should not be mixed in the solution for infusion because of the risk of precipitation.

Cannulae and catheters for intravenous use should be flushed with physiological salt-solution between administrations of ceftazidime and vancomycin to avoid precipitation.

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

Vial size		Amount of diluent to be added (ml)	Approximate concentration (mg/ml)
1 g Powder for solution for injection or infusion			
1 g	Intramuscular	3 ml	260
	Intravenous bolus	10 ml	90
	Intravenous infusion	50 ml*	20
2 g Powder for solution for injection or infusion			
2g	Intravenous bolus	10 ml	170
	Intravenous infusion	50 ml*	40
3 g Powder for solution for injection or infusion			
3 g	Intravenous bolus	15 ml	170
	Intravenous infusion	75 ml*	40

*Note: Addition should be in two stages.

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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 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 than you should
If you are accidentally given more than your prescribed dose, contact your doctor or nearest hospital straight away.
If you forget to be given Ceftazidime
If you miss an injection, you should have it as soon as possible. However, if it is almost time for your next injection, the missed injection will be skipped. Don't take a double dose (two injections at the same time) to make up for a missed dose.
If you stop using Ceftazidime
Don't stop taking Ceftazidime unless your doctor tells you to.
If you have 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.
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.

Contact a doctor or nurse immediately if you get any of these symptoms.
Other side effects
Common: 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
- increase in a type of white blood cell *(eosinophilia)* or in the number of cells that help the blood to clot
- increase in liver enzymes.

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

Very rare: may affect up to 1 in 10,000 people:
- inflammation or failure of the kidneys.

Not known: frequency cannot be estimated from the available data:
- pins and needles
- unpleasant taste in the mouth
- yellowing of the whites of the eyes or skin
- red blood cells destroyed too quickly, increase in a certain type of white blood cells, severe decrease in the number of white blood cells.

If you get any side effects talk to your doctor or nurse. This includes any possible side effect not listed in this leaflet.

5. How to store CEFTAZIDIME

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 label and carton after EXP. The expiry date refers to the last day of that month.
Store below 25°C.
Keep vial in the original outer carton.
Reconstituted/diluted solutions should be used immediately.
Discard any unused solution.
Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Ceftazidime contains
The active substance ceftazidime as ceftazidime pentahydrate.
One vial of 3 g Powder for solution for injection or infusion contains ceftazidime pentahydrate, equivalent to 3 g of ceftazidime.
The other ingredients are:
Sodium carbonate, anhydrous (E500)
What Ceftazidime looks like and contents of the pack
The reconstituted solution is light yellow to amber in colour. The colour depends on the amount of liquid used to dissolve the powder and the concentration of ceftazidime in the reconstituted solution. The antibiotic effect of the solution is not affected by its colour.
1 g, 2 g and 3 g Powder for solution for injection or infusion:
Ceftazidime is available as Powder for solution for injection or infusion. The powder is white to almost white. The powder is supplied as a single dose vial packed in a carton box. Each carton box contains 10 vials.
Marketing Authorisation Holder
Stragen UK Limited, Castle Court, 41 London Road, Reigate, Surrey RH2 9RJ
Manufacturer
Mitim S.R.L., Via Cacciamali 34/38, 25125 Brescia, Italy
This medicinal product is authorised in the Member States of the EEA under the following names:
Denmark: ..... Ceftazidim Stragen
United Kingdom: ..... Ceftazidime

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Solutions range in colour from light yellow to amber depending on concentration, diluent and storage conditions used. Within the stated recommendations, the product potency is not adversely affected by such colour variation.

Ceftazidime is compatible with:
- Water for injection
- Sodium chloride solution 9 mg/ml (0.9 %) solution for injection
- Glucose 50 mg/ml (5 %)
- Glucose 50 mg/ml (5 %) in 0.9% sodium chloride injection

Ceftazidime may be constituted for intramuscular use with 1% lidocaine solution for injection.

1 g, 2 g, 3 g Powder for solution for injection or infusion:
Preparation of solutions for bolus injection

1. Insert the syringe needle through the vial closure and inject the recommended volume of diluent. Remove the syringe needle.
2. Shake to dissolve: carbon dioxide is released and a clear solution will be obtained in about 1 to 2 minutes.
3. Invert the vial. With the syringe plunger fully depressed, insert the needle through the vial closure and withdraw the total volume of solution into the syringe (the pressure in the vial may aid withdrawal). Ensure that the needle remains within the solution and does not enter the head space. The withdrawn solution may contain small bubbles of carbon dioxide, they may be disregarded.

These solutions may be given directly into the vein or introduced into the tubing of a giving set if the patient is receiving parenteral fluids.

1 g, 2 g, 3 g Powder for solution for injection or infusion:
Preparation of solutions for i.v. infusion:

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

1. Introduce the syringe needle through the vial closure and inject 10 ml of the diluent for the 1 g and 2 g vials, and 15 ml for the 3 g vial.
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. Add a further 40 ml of diluent for the 1 g and 2 g vials and 60 ml for the 3 g vial. Remove the vent needle.
5. Administer by intravenous infusion over 15 to 30 min. Additional pressure that may develop in the vial especially after storage should be relieved prior to administration to the patient

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.
The solution should only be used if the solution is clear and free from particles.