Package leaflet: Information for the patient

hameln

Ceftazidime 500 mg powder for solution for injection
Ceftazidime 1 g powder for solution for injection/infusion
Ceftazidime 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 or nurse.
- If you get any side effects talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Ceftazidime 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 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** 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.

Take special care with Ceftazidime

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

Tell your doctor if you are taking, have recently taken or might take any other medicines. 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 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 (main component of cooking/table salt)

You need to take this into account if you are on a controlled sodium diet.

Ceftazidime 500 mg
This medicine contains 25 mg sodium in each vial. This is equivalent to 1.25% of the recommended maximum daily dietary intake of sodium for an adult.

Ceftazidime 1 g
This medicine contains 50 mg sodium in each vial. This is equivalent to 2.5% of the recommended maximum daily dietary intake of sodium for an adult.

Ceftazidime 2 g
This medicine contains 100 mg sodium in each vial. This is equivalent to 5% of the recommended maximum daily dietary intake of sodium for an adult.

Reconstitution of solution – see "Instructions for reconstitution/dilution" on the end of this leaflet. Total content of sodium should be counted including sodium from dilutant. To obtain additional information on sodium content in dilutant please see leaflet of dilutant.

3. How Ceftazidime is given

Ceftazidime is usually given by a doctor or nurse.

Ceftazidime 500 mg powder for solution for injection
Ceftazidime is given as an injection directly into a vein or into a muscle.

Ceftazidime 1 g powder for solution for injection/infusion
Ceftazidime can be given as a drip (intravenous infusion) or as an injection directly into a vein or into a muscle.

Ceftazidime 2 g powder for solution for injection/infusion
Ceftazidime can be given as a drip (intravenous infusion) or as an injection directly into a vein.

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 years

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

The following information is intended for healthcare professionals only: hameln

Ceftazidime 500 mg powder for solution for injection
Ceftazidime 1 g powder for solution for injection/infusion
Ceftazidime 2 g powder for solution for injection/infusion

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

The reconstituted product is chemically and physically stable:
- at 2°C to 8°C for 24 hours;
- below 25°C for 3 hours.

The reconstituted product does not require protection from light.

From a microbiological point of view, once opened, the product 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 2-8°C, unless reconstitution has taken place in controlled and validated aseptic conditions.

Special precaution for storage

This medicine does not require any special temperature storage conditions. Store in original packaging in order to protect from light.

Special precautions for disposal and other handling

All sizes of vials of Ceftazidime 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 reconstitution/dilution
See table for addition volumes and solution concentrations, which may be useful when fractional doses are required.

Presentation	Route of administration	Amount of diluent to be added [ml]	Approx. ceftazidime concentration [mg/ml]
500 mg	intramuscular injection	1.5	260
	intravenous bolus	5	90
1 g	intramuscular injection	3	260
	intravenous bolus	10	90
	intravenous infusion	50*	20
2 g	intravenous bolus	10	170
	intravenous infusion	50*	40

* Addition should be in two stages

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.
Solutions may range in colour from colorless to pale-yellow depending on concentration and storage conditions used. Within the stated recommendations, product potency is not adversely affected by such colour variations.
Recommended dilution media are:
- 0.9% sodium chloride;
- 5% glucose solution for infusion;
- 5% glucose et 0.9% sodium chloride, 1:1;
- 5% glucose et 0.9% sodium chloride, 2:1;
- Ringer solution;
- lactated Ringer's solution;
- water for injection.

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 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

If you miss an injection, you should have it as soon as possible. Don't take a double dose (two injections at the same time) to make up for a missed dose, just take your next dose at the usual time.

Don't stop taking Ceftazidime

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:

- 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 to Yellow Card Scheme via 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

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 medicine does not require any special temperature storage conditions. Store in original packaging in order to protect from light.

The reconstituted product is chemically and physically stable:

- at 2°C to 8°C for 24 hours;
- below 25°C for 3 hours.

The reconstituted product does not require protection from light.

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 contains

- Ceftazidime is available in the following strengths: 2 g, 1 g and 500 mg. The active substance is 2 g, 1 g or 500 mg of ceftazidime (present as ceftazidime pentahydrate).
- The only other ingredient is sodium carbonate.

What Ceftazidime looks like and contents of the pack

Ceftazidime is a white or pale-yellow powder filled in glass vial (15 ml for Ceftazidime 500 mg and 20 ml for Ceftazidime 1 g, 2 g) with a bromobutyl rubber stopper, aluminium cap or aluminium cap and plastic flip-off. Pack contains 10 vials.

Your doctor, pharmacist or nurse will make the injection or infusion up with water for Injections or a suitable infusion fluid. When made up, Ceftazidime varies in colour from colorless to pale-yellow. This is perfectly normal.

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Ceftazidime at concentrations between 1 mg/ml and 40 mg/ml is compatible with the listed above diluents.
Ceftazidime may be constituted for intramuscular use with 1% lidocaine hydrochloride for injections.

Preparation of solutions for bolus injection

1. Insert the syringe needle through the vial closure and inject the recommended volume of diluent.
   The vacuum may assist entry of the 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. Ceftazidime is compatible with the intravenous fluids listed above.

Preparation of solutions for intravenous infusion

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

1. Puncture the stopper with a needle and inject 10 ml of the diluent into a 1 g and 2 g vial.
2. Withdraw the needle and shake the vial to obtain 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 making up a total volume of at least 50 ml, 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 unused medicinal product or waste material should be disposed of in accordance with local requirements.

Incompatibilities

Ceftazidime is less stable in sodium bicarbonate solution than in other intravenous fluids. It is not recommended as a diluent.

Ceftazidime and aminoglycosides should not be mixed in the same giving set or syringe. Precipitation has been reported with vancomycin added to ceftazidime in solution. Therefore, the application kit and intravenous access should be flushed between the administration of these two drugs.