PACKAGE LEAFLET

Package leaflet: Information for the user

Ceftazidime hameln 1 g powder for solution for injection/infusion
Ceftazidime hameln 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 hameln is and what it is used for

Ceftazidime hameln 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 hameln 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 hameln 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 hameln

You must not be given Ceftazidime hameln:
- **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 hameln.

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

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 hameln. 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 hameln.

Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS), acute generalized 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.

If you need a blood or urine test
Ceftazidime hameln 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 hameln.

Other medicines and Ceftazidime hameln
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 hameln 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 hameln:
- 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 hameln against the risk to your baby.

Driving and using machines
Ceftazidime hameln 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 hameln contains sodium (main component of cooking/table salt)
You need to take this into account if you are on a controlled sodium diet.

Ceftazidime hameln 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 hameln 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 hameln is given

Ceftazidime hameln is usually given by a doctor or nurse.

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

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

Ceftazidime hameln 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 hameln 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 hameln 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 hameln 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 hameln 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.

Patients with kidney problems
You may be given a different dose to the usual dose. The doctor or nurse will decide how much Ceftazidime hameln 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 hameln 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 hameln
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 hameln
Don't stop taking Ceftazidime hameln 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.
Seek medical attention immediately if you notice any of the following symptoms:
- 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 reaction**. Signs include **raised and itchy rash**, **swelling**, sometimes of the face or mouth causing **difficulty in breathing**.
- 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.**

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
- 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).

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 HPRA Pharmacovigilance Website: www.hpra.ie.
By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Ceftazidime hameln

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 on the carton and vial label after EXP. The expiry date refers to the last day of that month.

Do not use this medicine if you notice any visible signs of deterioration.

This medicine does not require any special temperature storage conditions. Keep the vial in the outer carton in order to protect from light.

After reconstitution and dilution:
Chemical and physical in-use stability has been demonstrated for 3 hours at 25°C and 24 hours at 2 to 8°C. The reconstituted and diluted products do not require protection from light.

From a microbiological point of view, unless the method of reconstitution and dilution precludes the risk of contamination, the product should be used immediately.
If not used immediately, in use storage times and conditions are the responsibility of the user.

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 hameln contains
- The active substance is ceftazidime. Each vial contains ceftazidime pentahydrate equivalent to 1 g or 2 g ceftazidime.
- The other ingredient is sodium carbonate.

What Ceftazidime hameln looks like and contents of the pack
Ceftazidime hameln is a white or pale-yellow powder in a glass vial. Each 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 hameln varies in colour from colorless to pale-yellow. This is perfectly normal.

Marketing Authorisation Holder

hameln pharma gmbh
Inselstraße 1
31787 Hameln
Germany

Manufacturer
hameln rds s.r.o.
Horna 36
90001 Modra
Slovakia

This medicine is authorised in the Member States of the European Economic Area under the following names:

Austria	Ceftazidim hameln 1 g Pulver zur Herstellung einer Injektions-/Infusionslösung Ceftazidim hameln 2 g Pulver zur Herstellung einer Injektions-/Infusionslösung
Belgium	Ceftazidim hameln 1 g ~~poeder~~ voor oplossing voor injectie/infusie / Pulver zur Herstellung einer Injektions-/Infusionslösung / poudre pour solution injectable/pour perfusion Ceftazidim hameln 2 g poeder voor oplossing voor injectie/infusie / Pulver zur Herstellung einer Injektions-/Infusionslösung / poudre pour solution injectable/pour perfusion
Czech republik	Ceftazidime hameln
Denmark	Ceftazidim “hameln”
Finland	Ceftazidim hameln 1 g injektio-/infuusiokuiva-aine, liuosta varten Ceftazidim hameln 2 g injektio-/infuusiokuiva-aine, liuosta varten
Germany	Ceftazidim hameln 1 g Pulver zur Herstellung einer Injektions-/Infusionslösung Ceftazidim hameln 2 g Pulver zur Herstellung einer Injektions-/Infusionslösung
Ireland	Ceftazidime hameln 1 g powder for solution for injection/infusion Ceftazidime hameln 2 g powder for solution for injection/infusion
Italy	Ceftazidime hameln
Netherland	Ceftazidim hameln 1 g poeder voor oplossing voor injectie/infusie Ceftazidim hameln 2 g poeder voor oplossing voor injectie/infusie
Norway	Ceftazidim hameln
Slovak republik	Ceftazidime hameln 2 g prášok na injekčný/infúzny roztok Ceftazidime hameln 1 g prášok na injekčný/infúzny roztok
Sweden	Ceftazidim hameln 1 g Pulver till injektions-/infusionsvätska, lösning Ceftazidim hameln 2 g Pulver till injektions-/infusionsvätska, lösning

This leaflet was last revised in 15.08.2025.

The following information is intended for healthcare professionals only:

Ceftazidime hameln 1 g powder for solution for injection/infusion
Ceftazidime hameln 2 g powder for solution for injection/infusion

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

Special precausion for storage
This medicine does not require any special temperature storage conditions. Keep the vial in the outer carton in order to protect from light.

Special precautions for disposal and other handling
All sizes of vials of Ceftazidime hameln 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]
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 and 0.9% sodium chloride, 1:1;
- 5% glucose and 0.9% sodium chloride, 2:1;
- Ringer solution;
- lactated Ringer's solution;
- water for injection.

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. The clear solution will be obtained in about 1 to 2 minutes.
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.