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Package leaflet: Information for the user
Ceftazidime 1g powder for solution for injection or infusion
Ceftazidime 2g powder for solution for injection or infusion

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.
- This medicine has been prescribed to 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

The name of the medicine is ceftazidime 1g powder for solution for injection or infusion and ceftazidime 2g powder for solution for injection or infusion. In the rest of this leaflet it is called ceftazidime.

What is in this leaflet

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 ceftazidime if you think that this applies to you; you must not be given ceftazidime.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before you start on 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 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 or pharmacist 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
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.
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.

Important information about some of the ingredients of ceftazidime
Ceftazidime contains sodium
This medicine contains 52mg sodium (main component of cooking/table salt) in each 1g vial. This is equivalent to 2.6% of the recommended maximum daily dietary intake of sodium for an adult.
This medicine contains 104mg sodium (main component of cooking/table salt) in each 2g vial. This is equivalent to 5.2% of the recommended maximum daily dietary intake of sodium for an adult.

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

Babies (over 2 months) and children who weigh less than 40kg
For every 1kg the baby or child weighs, they'll be given 100 to 150mg of ceftazidime per day divided in three doses. Maximum 6g per day.

Adults and adolescents who weigh 40kg or more
1 to 2g of ceftazidime three times daily. Maximum of 9g per day.

Patients over 65
The daily dose should not normally exceed 3g 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 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. However, if it is almost time for your next injection, skip the missed injection. Do not take a double dose (two injections at the same time) to make up for a forgotten dose.

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

Information for Health Care Professionals
Ceftazidime 1g powder for solution for injection or infusion and Ceftazidime 2g powder for solution for injection or infusion

Dosage and Administration Information Only
Please refer to the Summary of Product Characteristics for further information
- Posology and method of administration

Method of administration
The dose depends on the severity, susceptibility, site and type of infection and on the age and renal function of the patient.
Ceftazidime should be administered by intravenous injection or infusion, or by deep intramuscular injection.
Recommended intramuscular injection sites are the upper outer quadrant of the *gluteus maximus* or lateral part of the thigh.
Ceftazidime solutions may be given directly into the vein or introduced into the tubing of a giving set if the patient is receiving parenteral fluids. The standard recommended route of administration is by intravenous intermittent injection or intravenous continuous infusion. Intramuscular administration should only be considered when the intravenous route is not possible or less appropriate for the patient.

Posology
Adults and children ≥ 40kg

Intermittent administration	
Infection	Dose to be administered
Broncho-pulmonary infections in cystic fibrosis	100 to 150mg/kg/day every 8h, maximum 9g per day
Febrile neutropenia	2g every 8h
Nosocomial pneumonia	
Bacterial meningitis	
Bacteraemia*	
Bone and joint infections	1-2g every 8h
Complicated skin and soft tissue infections	
Complicated intra-abdominal infections	
Peritonitis associated with dialysis in patients on CAPD	
Complicated urinary tract infections	1-2g every 8h or 12h
Peri-operative prophylaxis for transuretheral resection of prostate (TURP)	1g at induction of anaesthesia, and a second dose at catheter removal
Chronic suppurative otitis media	1g to 2g every 8h
Malignant otitis externa	
Continuous Infusion	
Infection	Dose to be administered
Febrile neutropenia	Loading dose of 2g followed by a continuous infusion of 4 to 6g every 24h[†]
Nosocomial pneumonia	
Broncho-pulmonary infections in cystic fibrosis	
Bacterial meningitis	
Bacteraemia*	Loading dose of 2g followed by a continuous infusion of 4 to 6g every 24h[†]
Bone and joint infections	
Complicated skin and soft tissue infections	
Complicated intra-abdominal infections	
Peritonitis associated with dialysis in patients on CAPD	Loading dose of 2g followed by a continuous infusion of 4 to 6g every 24h[†]

[†] In adults with normal renal function 9g/day has been used without adverse effects.
* When associated with, or suspected to be associated with, any of the infections listed in section 4.1.

Children < 40kg

Infants and toddlers >2 months and children < 40kg	Infection	Usual dose
Intermittent Administration		
	Complicated urinary tract infections	100-150mg/kg/day in three divided doses, maximum 6g/day
	Chronic suppurative otitis media	
	Malignant otitis externa	
	Neutropenic children	150mg/kg/day in three divided doses, maximum 6g/day
	Broncho-pulmonary infections in cystic fibrosis	
	Bacterial meningitis	
	Bacteraemia*	
	Bone and joint infections	100-150mg/kg/day in three divided doses, maximum 6g/day
	Complicated skin and soft tissue infections	
	Complicated intra-abdominal infections	
	Peritonitis associated with dialysis in patients on CAPD	
Continuous Infusion		
	Febrile neutropenia	Loading dose of 60-100mg/kg followed by a continuous infusion 100-200mg/kg/day, maximum 6g/day
	Nosocomial pneumonia	
	Broncho-pulmonary infections in cystic fibrosis	
	Bacterial meningitis	
	Bacteraemia*	
	Bone and joint infections	
	Complicated skin and soft tissue infections	
	Complicated intra-abdominal infections	
	Peritonitis associated with dialysis in patients with CAPD	
Neonates and infants ≤ 2 months	Infection	Usual dose
Intermittent Administration		
	Most infections	25-60mg/kg/day in two divided doses[‡]

[‡] In neonates and infants ≤ 2 months, the serum half life of ceftazidime can be three to four times that in adults.
* Where associated with or suspected to be associated with any of the infections listed in section 4.1.

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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 national reporting systems listed below.

United Kingdom:

Yellow Card Scheme Website: 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 carton and vial. The expiry date refers to the last day of that month.
- The vials should not be stored above 25º C.
- Keep the vial in the outer carton in order to protect from light.
- Chemical and physical in-use stability has been demonstrated for eight hours at 25º C and 24 hours at 4º C. 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 2-8º C, unless reconstitution has taken place in controlled and validated aseptic conditions. For single use only. Once reconstituted, any unused portion of solution should be discarded.
- Do not use this medicine if you notice that the solution contains particles or is cloudy.

Do not throw away any medicines via wastewater or household waste. 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 is ceftazidime as ceftazidime pentahydrate.
Each vial contains the equivalent of 1g or 2g of ceftazidime. It also contains the ingredient, sodium carbonate.
The sodium content per vial is approximately 52mg (2.26 mmol) for the 1g vial and 104mg (4.52 mmol) for the 2g vial.

What ceftazidime looks like and contents of the pack

Ceftazidime is a white to cream coloured powder, which must be made into a solution before injection or infusion. It is available in packs of 1, 5 or 10 vials. Not all pack sizes are marketed.

X-PIL Information

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:
0800 198 5000 (UK Only)
Please be ready to give the following information:

Product Name	Reference Number
Ceftazidime 1g powder for solution for injection or infusion	29831/0031
Ceftazidime 2g powder for solution for injection or infusion	29831/0032

This is a service provided by the Royal National Institute of Blind People.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK
Manufacturer: CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, UK

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Paediatric population
The safety and efficacy of ceftazidime administered as continuous infusion to neonates and infants ≤ 2 months has not been established.

Elderly
In view of age related reduced clearance of ceftazidime in elderly patients, the daily dose should not normally exceed 3g in those over 80 years of age.

Hepatic impairment
Available data do not indicate the need for dose adjustment in mild or moderate liver function impairment. There are no study data in patients with severe hepatic impairment (see also section 5.2). Close clinical monitoring for safety and efficacy is advised.

Renal impairment
Ceftazidime is excreted unchanged by the kidneys. Therefore, in patients with impaired renal function, the dosage should be reduced (see also section 4.4).
An initial loading dose of 1g should be given. Maintenance doses should be based on creatinine clearance. For recommended maintenance doses of ceftazidime in renal impairment (including haemodialysis and peritoneal dialysis), follow the dosage recommendations in the SPC.

• Overdose

Overdose can lead to neurological sequelae including encephalopathy, convulsion and coma.
Symptoms of overdose can occur if the dose is not reduced appropriately in patients with renal impairment. Serum levels of ceftazidime can be reduced by haemodialysis or peritoneal dialysis.

• Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products. Ceftazidime is less stable in Sodium Bicarbonate Injection than 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 when vancomycin has been added to ceftazidime in solution. Therefore, it would be prudent to flush giving sets and intravenous lines between administration of these two agents.
Ceftazidime is incompatible with aminophylline. There is a possible incompatibility with pentamide.

• Instructions for use/handling

For single use. Discard any unused contents.
Instructions for reconstitution: See table for addition volumes and solution concentrations, which may be useful when fractional doses are required.

PREPARATION OF SOLUTION

INTRAMUSCULAR INJECTION

Strength	Diluent	Amount of diluent to be added (ml)	Approximate concentration (mg/ml)	Approximate available volume (ml)	Approximate displacement volume (ml)
1g	0.5% lidocaine	3ml	278	3.6ml	0.6ml
	1% lidocaine	3ml	270	3.7ml	0.7ml

INTRAVENOUS BOLUS

Strength	Diluent	Amount of diluent to be added (ml)	Approximate concentration (mg/ml)	Approximate available volume (ml)	Approximate displacement volume (ml)
1g	Water for Injection	10ml	92	10.9ml	0.9ml
2g	Water for Injection	10ml	172	11.6ml	1.6ml

INTRAVENOUS INFUSION

Strength	Diluent (see full list of compatible diluents below table)	Amount of diluent to be added (ml)[#]	Approximate concentration (mg/ml)	Approximate available volume (ml)	Approximate displacement volume (ml)
1g	Compatible diluent list below	50ml	20	---	---
2g	0.9% sodium chloride	50ml	39	51.5ml	1.5ml
	5% glucose	50ml	39	51.9ml	1.9ml

[#]Note: addition should be in two stages. See preparation for intravenous infusion instructions below.

Compatible diluents for intravenous infusion

Ceftazidime at concentrations between 1mg/ml and 40mg/ml is compatible with the following diluent solutions for intravenous infusion preparation:

- Sodium Chloride 0.9%
- Ringer Solution
- Ringer Lactate Solution
- Glucose 5%
- Glucose 10%
- Glucose 5% and Sodium Chloride 0.9%
- Glucose 5% and Sodium Chloride 0.45%
- Glucose 5% and Sodium Chloride 0.2%
- Dextran 40%/10% and Sodium Chloride 0.9%
- Dextran 70%/6% and Sodium Chloride 0.9%

Solutions range from light yellow to amber depending on concentration, diluent and storage conditions used.
All sizes of vials as supplied are under reduced pressure. As the product dissolves, carbon dioxide is released and a positive pressure develops. For ease of use, it is recommended that the following techniques of reconstitution are adopted.

Preparation of solution for bolus injection:

1. Insert the syringe needle through the vial closure and inject 10ml of Water for Injection. 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.

Preparation of solution for intravenous infusion:

Prepare using a total of 50ml of compatible diluent, added in TWO stages as follows:

1. Insert the syringe needle through the vial closure and inject 10ml of Water for Injection or one of the listed compatible diluent solutions for intravenous infusion preparation to reconstitute. The vacuum may assist entry of the diluent. Remove the syringe needle.
2. Shake to dissolve: carbon dioxide is released and a clear solution 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 the final delivery vehicle (e.g. mini-bag or burette-type set) and add 40ml of compatible diluent* to make up a total volume of approximately 50ml and administer by slow intravenous infusion over 20 to 30 minutes.

*For the second stage of preparation, use Sodium Chloride 0.9%, Glucose 5% or one of the listed compatible diluent solutions for intravenous infusion preparation, as Water for Injection produces hypotonic solutions when used at higher concentrations.
Ceftazidime at concentrations between 1mg/ml and 40mg/ml is compatible with the diluent solutions for intravenous infusion preparation listed above.
NOTE: To preserve product sterility, it is important that a gas relief needle is not inserted through the vial closure before the product has dissolved.

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