PACKAGE LEAFLET: INFORMATION FOR THE USER

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

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 cephalosporin.

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 USE CEFTAZIDIME

Do not use Ceftazidime
- if you are allergic (hypersensitive) 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.

Warnings and precautions
Talk to your doctor or nurse before using 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 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 using, have recently used or might use any other medicines. This includes medicines that you have bought 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 and breast feeding
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.

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

Ceftazidime content	Amount of sodium per vial
1 g	52 mg
2 g	104 mg

3. HOW TO USE CEFTAZIDIME

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 is:
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.

Use in children:
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 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. 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 any questions ask your doctor or nurse.

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

The following information is intended for medical or healthcare professionals only:

In-use storage conditions
After reconstitution and further dilution, the drug product should be used immediately.

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.

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

* Note: Addition should be in two stages

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

Ceftazidime at concentrations between 1 mg/ml and 40 mg/ml is compatible with the following solutions for injection:
- 0.9% sodium chloride
- 0.9% sodium chloride and 5% dextrose
- 10% dextrose

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 (up to 1 in 10 people are affected)
- 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 (up to 1 in 100 people are affected)
- 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.

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 or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in:
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

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 label and carton after EXP.

Store below 25ºC.
Before reconstitution store in the original carton in order to protect from light.

The hospital will keep Ceftazidime according to the correct storage conditions, and will ensure that it will be used within its validity.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Ceftazidime contains

- The active substance is ceftazidime.
  Ceftazidime 1 g
  Each vial contains ceftazidime 1 g (as penahydrate).
  Ceftazidime 2 g
  Each vial contains ceftazidime 2 g (as penahydrate).
- The other ingredient is sodium carbonate.

What Ceftazidime looks like and contents of the pack
Ceftazidime is a white or pale yellow powder. It is available in glass vials (1 or 10 vials per pack).
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Hikma Farmacêutica (Portugal), S.A.
Estrada do Rio da Mó, nº8, 8A, 8B, Fervença
2705-906 Terrugem SNT, Portugal

Distributed by:
Consilient Health (UK) Ltd.
No. 1 Church Road, Richmond upon Thames, Surrey, TW9 2QE

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria:	Ceftazidim Hikma 500 mg Pulver zur Herstellung einer Injektionslösung Ceftazidim Hikma 1 g Pulver zur Herstellung einer Injektionslösung oder Infusionslösung Ceftazidim Hikma 2 g Pulver zur Herstellung einer Injektionslösung oder Infusionslösung
Germany:	Ceftazidim Hikma 500 mg Pulver zur Herstellung einer Injektionslösung Ceftazidim Hikma 1 g Pulver zur Herstellung einer Injektionslösung oder Infusionslösung Ceftazidim Hikma 2 g Pulver zur Herstellung einer Injektionslösung oder Infusionslösung
Ireland:	Ceftazidime 500mg, Powder for solution for injection Ceftazidime 1g, Powder for solution for injection/infusion Ceftazidime 2g, Powder for solution for injection/infusion
Portugal:	Ceftazidima Hikma 500mg, Pó para solução injetável Ceftazidima Hikma 1g, Pó para solução injetável ou para perfusão Ceftazidima Hikma 2g, Pó para solução injetável ou para perfusão
United Kingdom:	Ceftazidime 1g, Powder for solution for injection/infusion Ceftazidime 2g, Powder for solution for injection/infusion

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Ceftazidime may be reconstituted for intramuscular use with 0.5% or 1% Lidocaine Hydrochloride solution for injection, obtained solutions should be used immediately after preparation

- Ceftazidime 1 g, 2 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. 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 5 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 an infusion set if the patient is receiving parenteral fluids.

- Ceftazidime 1 g, 2 g powder for solution for injection or infusion:

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

Prepare using a total of 50 ml of compatible diluent, added in TWO stages as described 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 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.

For single use only. Any unused product or waste material should be disposed of in accordance with local requirements.