Package leaflet: Information for the patient

C-Zid 1.0 g Injection
(ceftazidime for Injection)

Read all of this leaflet carefully before you start taking 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 pharmacist.
- 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.

What is in this leaflet:

1. What C-Zid 1.0 g is and what it is used for

C-Zid 1.0 g 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.

C-Zid 1.0 g is used to treat severe bacterial infections of:
- the lungs or chest (lower RTI)
- the lungs and bronchi in patients suffering from cystic fibrosis
- the skin and soft tissues
- the urinary tract
- serious bloodstream infections
- the bones and joints
- inflammatory condition of lining of uterus, inflammation of parametrium, and other infections of the female genital tract
- the abdomen and abdominal wall (peritonitis)
- the brain (meningitis)

2. What you need to know before you are given C-Zid 1.0 g

You must not be given C-Zid 1.0 g:
C-Zid 1.0 g is contraindicated in patients who have shown hypersensitivity or are allergic to ceftazidime or the cephalosporin group of antibacterial drugs or any of the other ingredients of this medicine.

Take special care with C-Zid 1.0 g
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 this medicine. 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 injection.

Clostridium difficile associated diarrhea (CDAD) had been reported with use of nearly all antibacterial agents, including ceftazidime injection, and might range in severity from mild diarrhea (a few loose, watery stools in a day) to fatal colitis (inflammation of the inner lining of the colon). CDAD must be considered in patients who present with diarrhea following antibacterial drug use. Careful medical history is necessary since CDAD had been reported to occur over two months after the administration of antibacterial agents.

Increased levels of ceftazidime in patients with renal problems could lead to fits, disease in which the functioning of the brain is affected (encephalopathy), stage of prolonged consciousness (coma), inability to maintain sustained posture (asterixis), neuromuscular excitability and involuntary muscle movement (myoclonia).

The total daily dosage will be reduced when ceftazidime is given to patients with renal problems.

If you need a blood or urine test
The administration of ceftazidime might result in a false-positive reaction for glucose in the urine when using Clinitest® tablets, Benedict's solution, or Fehling's solution. It is recommended that glucose tests based on enzymatic glucose oxidase reactions be used.

Other medicines and C-Zid 1.0 g
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 C-Zid injection 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
• contraceptives
→ Tell your doctor if this applies to you.

Pregnancy, breast-feeding and fertility
Ask your doctor for advice before you are given C-Zid injection:
• If you are pregnant, think you might be pregnant or are planning to become pregnant
• If you are breast-feeding
Your doctor will consider the benefit of treating you with this medicine against the risk to your baby.

Driving and using machines

There are no studies available on the effects on the ability to drive and use machines have been performed. However, undesirable effects might occur (e.g. dizziness), which might influence the ability to drive and use machines.

3. How C-Zid 1.0 g is given

The usual adult dosage is 1 gram administered intravenously or intramuscularly every 8 to 12 hours. The dosage and route should be determined by the susceptibility of the causative organisms, the severity of infection, and the condition and renal function of the patient.

The guidelines for dosage of **C-Zid 1.0 g** were listed in table 1 below**Table *1***. The following dosage schedule is recommended.

Table 1. Recommended Dosage Schedule

	Dose	**Frequency**
Adult		
Usual recommended dosage	1 gram intravenous or intramuscular	every 8 to 12 hours
Uncomplicated urinary tract infection	250 mg intravenous or intramuscular	every 12 hours
Bone and joint infections	2 grams intravenous	every 12 hours
Complicated urinary tract infections	500 mg intravenous or intramuscular	every 8 to 12 hours
Uncomplicated pneumonia; mild skin and skin-structure infections	500 mg to 1 gram intravenous or intramuscular	every 8 hours
Serious gynecological and intra-abdominal infections	2 grams intravenous	every 8 hours
Meningitis	2 grams intravenous	every 8 hours
Very severe life-threatening infections, especially in immunocompromised patients	2 grams intravenous	every 8 hours
Lung infections caused by *Pseudomonas* spp. in patients with cystic fibrosis with normal renal function *	30 to 50 mg/kg intravenous to a maximum of 6 grams per day	every 8 hours
Neonates (0-4 weeks)	30 mg/kg intravenous	every 12 hours
Infants and children (1 month – 12 years)	30 to 50 mg/kg intravenous to a maximum of 6 grams per day †	every 8 hours

* Although clinical improvement had been shown, bacteriologic cures could not be expected in patients with chronic respiratory disease and cystic fibrosis.

† The higher dose should be reserved for immunocompromised pediatric patients or pediatric patients with cystic fibrosis or meningitis.

Impaired Hepatic Function

No adjustment in dosage is required for patients with hepatic dysfunction.

Impaired Renal Function

Ceftazidime is excreted by the kidneys, almost exclusively by glomerular filtration. Therefore, in patients with impaired renal function (glomerular filtration rate [GFR] <50 mL/min), it is recommended that the dosage of ceftazidime be reduced to compensate for its slower excretion.

In patients with suspected renal insufficiency, an initial loading dose of 1 gram of **C-Zid 1.0 g** might be given. An estimate of GFR should be made to determine the appropriate maintenance dosage.

The recommended dosage is presented in table 2 below.

Table 2. Recommended Maintenance Dosages of C-Zid 1.0 g in Renal Insufficiency

NOTE: if the dose recommended in table above is lower than that recommended for patients with renal insufficiency as outlined in this tableTable *2*, the lower dose should be used.		
Creatinine Clearance (mL/min)	**Recommended Unit Dose of C-Zid 1.0 g**	**Frequency of Dosing**
50-31	1 gram	every 12 hours
30-16	1 gram	every 24 hours
15-6	500 mg	every 24 hours
Less than 5	500 mg	every 48 hours

When only serum creatinine is available, the following formula (Cockcroft's equation)1 might be used to estimate creatinine clearance. The serum creatinine should represent a steady state of renal function:

Males: Creatinine clearance (mL/min) = Weight (kg) x (140 – age)/72 x serum creatinine (mg/dL)
Females: 0.85 x male value

In patients with severe infections who would normally receive 6 grams of Ceftazidime Injection daily were it not for renal insufficiency, the unit dose given in the table above might be increased by 50% or the dosing frequency might be increased appropriately. Further dosing should be determined by therapeutic monitoring, severity of the infection, and susceptibility of the causative organism.

In pediatric patients as for adults, the creatinine clearance should be adjusted for body surface area or lean body mass, and the dosing frequency should be reduced in cases of renal insufficiency.

In patients undergoing hemodialysis, a loading dose of 1 gram is recommended, followed by 1 gram after each hemodialysis period.

C-Zid 1.0 g could also be used in patients undergoing intraperitoneal dialysis and continuous ambulatory peritoneal dialysis. In such patients, a loading dose of 1 gram of **C-Zid 1.0 g** might be given, followed by 500 mg every 24 hours. In addition to IV use, **C-Zid 1.0 g** could be incorporated in the dialysis fluid at a concentration of 250 mg for 2 L of dialysis fluid.

Note: Generally, **C-Zid 1.0 g** should be continued for 2 days after the signs and symptoms of infection have disappeared, but in complicated infections longer therapy might be required.

Method of Administration

C-Zid might be given intravenously or by deep IM injection into a large muscle mass such as the upper outer quadrant of the gluteus maximus or lateral part of the thigh. Intra-arterial administration should be avoided.

Intramuscular administration: For IM administration, **C-Zid** should be constituted with one of the following diluents: Sterile Water for Injection, Bacteriostatic Water for Injection, or 0.5% of 1% Lidocaine Hydrochloride Injection. Refer to table 3 below.

Intravenous administration: The IV route is preferable for patients with bacterial septicemia, bacterial meningitis, peritonitis, or other severe or life-threatening infections, or for patients who might be poor risks because of lowered resistance resulting from such debilitating conditions such as malnutrition, trauma, surgery, diabetes, heart failure, or malignancy, particularly if shock is present or pending.

For Direct intermittent IV administration, constitute **C-Zid** as directed in table 3 below with Sterile Water for Injection. Slowly inject directly into vein over a period of 3 to 5 minutes or give through the tubing of an administration set while the patient is also receiving one of the compatible fluids.

Intermittent IV infusion with a Y-type administration set could be accomplished with compatible solutions. However, during infusion of a solution containing ceftazidime, it is desirable to discontinue the other resolution.

Table 3 . Preparation of solutions of C-Zid

Size of Vial	Route	Amount of Diluent to be added (mL)	Approximate Ceftazidime Concentration (mg/mL)
1 g	Intramuscular	3 mL	333.3
1 g	Intravenous bolus	10 mL	100
1 g	Intravenous infusion	50 mL	20

Solutions of **C-Zid**, like those of most beta-lactam antibiotics, should not be added to solutions of aminoglycoside antibiotics because of potential interaction. However, if concurrent therapy with C-Zid and an aminoglycoside is indicated, each of these antibiotics could be administered separately to the same patient.

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.

5. How to store C-Zid 1.0 g

- 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, bottle label or blister after EXP. The expiry date refers to the last day of that month.
- 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.
- Store in a cool, dry place, below 25°C. Protect from light

6. Contents of the pack and other information

Ceftazidime

What C-Zid 1.0 g looks like and contents of the pack

White to almost white crystalline powder.

Pack sizes:

1 Vial

Marketing Authorisation Holder and Manufacturer

Emcure Pharmaceuticals Limited

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