CEFTAZIDIME VIATRIS

Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I given CEFTAZIDIME VIATRIS?

CEFTAZIDIME VIATRIS contains the active ingredient ceftazidime (as pentahydrate). CEFTAZIDIME VIATRIS is used to treat a wide range of infections caused by bacteria.

For more information, see Section <u>1. Why am I given</u> <u>CEFTAZIDIME VIATRIS?</u> in the full CMI.

2. What should I know before I am given CEFTAZIDIME VIATRIS?

You must not be given CEFTAZIDIME VIATRIS if you have ever had an allergic reaction to medicines containing cephalosporins or penicillins, or any of the ingredients listed at the end of the CMI. Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section <u>2. What should I know</u> before I am given CEFTAZIDIME VIATRIS? in the full CMI.

3. What if I am taking other medicines?

Some medicines and CEFTAZIDIME VIATRIS may interfere with each other.

A list of these medicines is in Section <u>3. What if I am</u> <u>taking other medicines?</u> in the full CMI.

4. How CEFTAZIDIME VIATRIS is given?

CEFTAZIDIME VIATRIS will always be prepared and given to you by a doctor or another healthcare professional. CEFTAZIDIME VIATRIS will be injected deep into muscle tissue or into a vein. When it is injected into a vein it may be given directly or through a 'drip'.

More instructions can be found in Section <u>4. How</u> <u>CEFTAZIDIME VIATRIS is given?</u> in the full CMI.

5. What should I know while I am given CEFTAZIDIME VIATRIS?

Things you should do	 If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being given CEFTAZIDIME VIATRIS.
	 Tell any other doctors, dentists and pharmacists who treat you that you are being given this medicine. If you are about to have any blood or urine tests, tell your doctor that you are being given this medicine. It may interfere with the results of some tests.
	 If you become pregnant while taking this medicine, tell your doctor immediately.
Things you should not do	 Do not use CEFTAZIDIME VIATRIS to treat any other

	complaints unless your doctor tells you to.
Driving or using machines	 Be careful driving or operating machinery until you know how CEFTAZIDIME VIATRIS affects you.

For more information, see Section <u>5. What should I know</u> while I am given CEFTAZIDIME VIATRIS? in the full CMI.

6. Are there any side effects?

Like other medicines, CEFTAZIDIME VIATRIS may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

For more information, including what to do if you have any side effects, see Section <u>6. Are there any side</u> <u>effects?</u> in the full CMI.

CEFTAZIDIME VIATRIS

Active ingredient(s): ceftazidime (as pentahydrate)

Consumer Medicine Information (CMI)

This leaflet provides important information about using CEFTAZIDIME VIATRIS. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using CEFTAZIDIME VIATRIS.

Where to find information in this leaflet:

1. Why am I given CEFTAZIDIME VIATRIS?

2. What should I know before I am given CEFTAZIDIME VIATRIS?

- 3. What if I am taking other medicines?
- 4. How CEFTAZIDIME VIATRIS is given?

5. What should I know while I am given CEFTAZIDIME VIATRIS?

6. Are there any side effects?

7. Product details

1. Why am I given CEFTAZIDIME VIATRIS?

CEFTAZIDIME VIATRIS is used to treat a wide range of infections caused by bacteria. These infections may affect the chest (bronchitis or pneumonia), ears, nose, throat, bladder and urinary tract, skin and soft tissue, stomach or bones.

This medicine belongs to a group of medicines called cephalosporins.

It works by killing the bacteria that cause these infections.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

CEFTAZIDIME VIATRIS is not addictive.

2. What should I know before I am given CEFTAZIDIME VIATRIS?

You must not be given CEFTAZIDIME VIATRIS if:

- you have ever had an allergic reaction to any medicine containing cephalosporins or penicillins
- you are allergic to any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

You must not be given this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If you are not sure whether you should be given this medicine, talk to your doctor.

Check with your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes.
- take any medicines for any other condition
- have or have had any of the following medical conditions; kidney problems, liver problems, colitis or any other stomach or bowel illness.

Tell your doctor if you are prescribed some urine or blood tests or if you are going to have a blood transfusion.

The results of some tests can be altered by CEFTAZIDIME VIATRIS.

If you have not told your doctor about any of the above, tell them before you start taking CEFTAZIDIME VIATRIS.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6. Are there any side effects</u>?

Pregnancy and breastfeeding

Tell your doctor if you are pregnant or plan to become pregnant.

Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you are breastfeeding.

CEFTAZIDIME VIATRIS is excreted in human milk in low concentrations. Therefore, it should be administered to breastfeeding women only if clearly needed.

Tell your doctor if your baby has any signs of diarrhoea or any other illness, or if you notice anything wrong.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and CEFTAZIDIME VIATRIS may interfere with each other. These include:

- some antibiotics called aminoglycosides
- diuretics, also called fluid or water tablets
- another antibiotic called chloramphenicol, since both medicines can stop each other working
- oral contraceptives ('the pill').

These medicines may be affected by CEFTAZIDIME VIATRIS or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect CEFTAZIDIME VIATRIS.

4. How CEFTAZIDIME VIATRIS is given?

How much is given

CEFTAZIDIME VIATRIS will always be prepared and given to you by a doctor or another healthcare professional.

Depending on the severity and type of infection, your weight, your age and how well your kidneys are working, your doctor will determine a suitable dosage.

How it is given

CEFTAZIDIME VIATRIS will be injected deep into muscle tissue or into a vein. When it is injected into a vein it may be given directly or through a 'drip'.

How long it is given for

CEFTAZIDIME VIATRIS should be administered for as long as recommended by your doctor.

If you are given too much CEFTAZIDIME VIATRIS

As your dose of CEFTAZIDIME VIATRIS will be determined and administered by a medical specialist, the chance of receiving an overdose is most unlikely. However, if an overdose should be given, your specialist will give the appropriate treatment.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital if you think you or anyone else may have been given too much CEFTAZIDIME VIATRIS

You should do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

5. What should I know while I am given CEFTAZIDIME VIATRIS?

Things you should do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being given CEFTAZIDIME VIATRIS. Tell any other doctors, dentists and pharmacists who treat you that you are being given this medicine.

If you are about to have any blood or urine tests, tell your doctor that you are being given this medicine.

It may interfere with the results of some tests.

If you become pregnant while taking this medicine, tell your doctor immediately.

Things you should not do

Do not use CEFTAZIDIME VIATRIS to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not stop using your medicine or lower the dosage without checking with your doctor.

Driving or using machines

Be careful driving or operating machinery until you know how CEFTAZIDIME VIATRIS affects you.

Certain side effects, such as dizziness and convulsions, have been reported with ceftazidime, which may affect some patient's ability to drive and use machines.

Looking after your medicine

CEFTAZIDIME VIATRIS will be stored in the pharmacy or on the ward.

Before opening:

Store in the original package at a temperature below 25°C. Protect from light.

After reconstitution:

To reduce microbiological hazard, use as soon as practicable after reconstitution/preparation. If storage is necessary, hold at 2-8°C for not more than 24 hours.

This medicine is for single use only. Any unused solution should be discarded.

Do not store CEFTAZIDIME VIATRIS or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking CEFTAZIDIME VIATRIS. Like other medicines, CEFTAZIDIME VIATRIS may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following list of side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Less serious side effects

Less serious side effects	What to do
 skin trouble such as a rash, red spots, itching, skin lumps, hives, blisters or peeling 	Speak to your doctor or nurse if you have any of these less serious side effects and they worry
 swelling of the eyelids, face or lips 	you.
 diarrhoea (even several weeks after your CEFTAZIDIME VIATRIS treatment) 	
 high temperature (fever) 	
 difficulty breathing 	
 bruising or bleeding 	
 shaking or muscle twitches 	

Less serious side effects	What to do
 wheezing, swelling of the lips/mouth, difficulty in breathing, hayfever, lumpy rash (hives) or fainting. These could be symptoms of an allergic reaction. 	

Serious side effects

Serious side effects	What to do
 pain or flaking skin where you had the injection headache stomach pain dizziness numbness or tingling nausea (feeling of sickness) or vomiting bad taste in mouth sore mouth or tongue vaginal discharge, genital itching. Reduced ability to think clearly or concentrate, memory loss, drowsiness, seizures, 	Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Serious side effects	What to do
muscle twitches and personality change.	
These symptoms may be related to a condition called encephalopathy.	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at <u>www.tga.gov.au/reporting-problems</u>.

By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What CEFTAZIDIME VIATRIS contains

Active ingredient (main ingredient)	Ceftazidime (as pentahydrate)
Other ingredients (inactive ingredients)	Sodium carbonate

Do not take this medicine if you are allergic to any of these ingredients.

What CEFTAZIDIME VIATRIS looks like

CEFTAZIDIME VIATRIS is a powder for injection and is a white or almost white, crystalline powder. The powder is reconstituted with sterile water prior to injection.

The reconstituted injection solution should be clear and light yellow to amber colour.

CEFTAZIDIME VIATRIS is available in packs of 10 vials in two different strengths:

- CEFTAZIDIME VIATRIS 1000 mg (AUST R 154398)
- CEFTAZIDIME VIATRIS 2000 mg (AUST R 154399)

Who distributes **CEFTAZIDIME VIATRIS**

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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