CEPHAZOLIN 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 using CEPHAZOLIN VIATRIS?

CEPHAZOLIN VIATRIS contains the active ingredient cefazolin sodium. CEPHAZOLIN VIATRIS is antibiotic used to treat infections in different parts of the body caused by bacteria.

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

2. What should I know before I use CEPHAZOLIN VIATRIS?

Do not use if you have ever had an allergic reaction to cefazolin sodium, or to any other cephalosporins, 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 use CEPHAZOLIN VIATRIS? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with CEPHAZOLIN VIATRIS and affect how it works.

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 is CEPHAZOLIN VIATRIS given?

CEPHAZOLIN VIATRIS must only be given by a doctor or nurse. Your doctor will decide what dose and how long you will receive CEPHAZOLIN VIATRIS.

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

5. What should I know while using CEPHAZOLIN VIATRIS?

Things you should do	 Remind any doctor, nurse, dentist or
	pharmacist you visit

	 that you are using CEPHAZOLIN VIATRIS. If the symptoms of your infection do not improve within a few days, or if they become worse, tell your doctor. If you get a sore white mouth or tongue or if you get severe diarrhoea, tell your doctor, pharmacist or nurse immediately.
Driving or using machines	 Be careful driving or operating machinery until you know how CEPHAZOLIN VIATRIS affects you. CEPHAZOLIN VIATRIS may cause dizziness in some people.
Looking after your medicine	 CEPHAZOLIN VIATRIS will be stored in the pharmacy or on the ward.

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

6. Are there any side effects?

Less serious side effects: oral thrush, vaginal thrush, diarrhoea, nausea or vomiting, or pain, redness and swelling where the injection was given. Serious side effects: severe abdominal cramps or stomach cramps, watery and severe diarrhoea, which may also be bloody, skin rash, itching or hives, swelling of the face, lips or tongue which may cause difficulty swallowing or breathing, chest pain in the context of allergic reactions, wheezing or shortness of breath, fever, signs of frequent infections such as fever, chills, sore throat and mouth ulcers, bleeding or bruising more easily than normal, seizures, changes in mental function, behaviour or state, and/or muscle jerk.

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.

CEPHAZOLIN VIATRIS

Active ingredient: cefazolin sodium

Consumer Medicine Information (CMI)

This leaflet provides important information about using CEPHAZOLIN 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 CEPHAZOLIN VIATRIS.

Where to find information in this leaflet:

1. Why am I using CEPHAZOLIN VIATRIS?

2. What should I know before I use CEPHAZOLIN VIATRIS?

- 3. What if I am taking other medicines?
- 4. How do I use CEPHAZOLIN VIATRIS?

5. What should I know while using CEPHAZOLIN VIATRIS?

6. Are there any side effects?

7. Product details

1. Why am I using CEPHAZOLIN VIATRIS?

CEPHAZOLIN VIATRIS contains the active ingredient cefazolin sodium. CEPHAZOLIN VIATRIS belongs to a group of antibiotics called cephalosporins. These antibiotics work by killing the bacteria that are causing your infection.

CEPHAZOLIN VIATRIS is an antibiotic used to treat infections in different parts of the body caused by bacteria.

Your doctor may have prescribed CEPHAZOLIN VIATRIS for another reason.

Ask your doctor if you have any questions about why CEPHAZOLIN VIATRIS has been prescribed for you.

CEPHAZOLIN VIATRIS is not addictive.

2. What should I know before I use CEPHAZOLIN VIATRIS?

Warnings

Do not use CEPHAZOLIN VIATRIS if:

 you are allergic to cefazolin sodium, or to any other cephalosporins, or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- asthma, wheezing, shortness of breath
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- skin rash itching or hives.

Always check the ingredients to make sure you can use this medicine.

 you have had a serious allergic reaction to any penicillins.

You may be more likely to have an allergic reaction to CEPHAZOLIN VIATRIS if you are allergic to penicillin medicines.

- the packaging is torn or shows signs of tampering.
- the expiry date on the pack has passed.

If you are not sure whether you should be given CEPHAZOLIN VIATRIS talk to your doctor or nurse.

Check with your doctor if you:

 have had any type of allergic reaction to any cephalosporin or penicillin medicines.

You may have an increased chance of being allergic to CEPHAZOLIN VIATRIS if you are allergic to any cephalosporins or penicillins.

- have any allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
- are pregnant or intend to become pregnant.
- are breast-feeding or intend to breast-feed.
- have or have had any medical conditions, including:
 - kidney disease
 - stomach or bowel problems

If you have not told your doctor about any of the above, tell them before you are given CEPHAZOLIN 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

Check with your doctor if you are pregnant or intend to become pregnant.

CEPHAZOLIN VIATRIS may affect your developing baby if you use it during pregnancy. Your doctor will discuss the risks and benefits of using CEPHAZOLIN VIATRIS during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

CEPHAZOLIN VIATRIS passes into breast milk and may affect your baby. Your doctor will discuss the risks and benefits of using CEPHAZOLIN VIATRIS when breastfeeding.

Use in children

CEPHAZOLIN VIATRIS is not recommended for use in premature infants or infants under one month of age. The safety of CEPHAZOLIN VIATRIS in premature infants and infants under one month of age has not been established.

3. What if I am taking other medicines?

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

Some medicines may interfere with CEPHAZOLIN VIATRIS and affect how it works. These include:

- probenecid, a medicine used to treat gout
- warfarin, a medicine used to prevent blood clots
- other antibiotics such as amikacin, gentamicin, tobramycin
- typhoid vaccine.

These medicines may be affected by CEPHAZOLIN VIATRIS or may affect how well it works. You may need to use different amounts of your medicine, or you may need to use different medicines. Your doctor will advise you.

Talk to your doctor about the need for an additional method of contraception while using CEPHAZOLIN VIATRIS.

Some antibiotics may decrease the effectiveness of some birth control pills.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using CEPHAZOLIN VIATRIS. Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect CEPHAZOLIN VIATRIS.

4. How is CEPHAZOLIN VIATRIS given?

CEPHAZOLIN VIATRIS must only be given by a doctor or nurse.

CEPHAZOLIN VIATRIS can be given:

- into a vein via a drip
- as a slow injection into a vein
- as a deep injection into a large muscle.

Your doctor will decide what dose and how long you will receive CEPHAZOLIN VIATRIS. This depends on your condition and whether you are taking any other medicines. For most infections, CEPHAZOLIN VIATRIS is usually given in divided doses throughout the day.

Sometimes only a single dose of CEPHAZOLIN VIATRIS is required for the treatment of certain infections.

If you are given too much CEPHAZOLIN VIATRIS

In the unlikely event of an overdose, your treating physician will know what to do.

If you are given too much CEPHAZOLIN VIATRIS you may experience redness, pain or inflammation where the injection was given, stomach upset, headaches, chills, dizziness, tingling or numbness of the hands and feet or seizures.

5. What should I know while using CEPHAZOLIN VIATRIS?

Things you should do

- If the symptoms of your infection do not improve within a few days, or if they become worse, tell your doctor.
- If you get severe diarrhoea, tell your doctor, pharmacist or nurse immediately. Do this even if it occurs several weeks after CEPHAZOLIN VIATRIS has been stopped.

Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care. Do not take any diarrhoea medicine without checking with your doctor.

 If you get a sore white mouth or tongue while using or soon after stopping CEPHAZOLIN VIATRIS, tell your doctor. Also tell your doctor if you get vaginal itching or discharge.

This may mean you have a fungal infection called thrush. Sometimes, the use of CEPHAZOLIN VIATRIS allows fungi to grow and the above symptoms to occur. CEPHAZOLIN VIATRIS does not work against fungi.

• If you become pregnant while you are using CEPHAZOLIN VIATRIS, tell your doctor immediately.

- If you are about to start taking any new medicine, tell your doctor and pharmacist that you are using CEPHAZOLIN VIATRIS.
- If you have to test your urine for sugar while you are being given CEPHAZOLIN VIATRIS, make sure your doctor knows which type of test you use.

CEPHAZOLIN VIATRIS may affect the results of some of these tests.

 Tell all the doctors, dentists and pharmacists who are treating you that you are using CEPHAZOLIN VIATRIS.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how CEPHAZOLIN VIATRIS affects you.

CEPHAZOLIN VIATRIS may cause dizziness in some people. Make sure you know how you react to CEPHAZOLIN VIATRIS before you drive a car, operate machinery or do anything else that may be dangerous if you are affected.

Looking after your medicine

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

The powder for injection is kept in a cool, dry place, protected from light and moisture, where the temperature stays below 25°C.

After reconstitution Store at 2 to 8°C. Refrigerate. Do not freeze. (Use within 24 hours after initial reconstitution).

6. Are there any side effects?

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well after you are given CEPHAZOLIN VIATRIS.

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects	What to do
 oral thrush – white, furry, sore tongue and mouth vaginal thrush – sore and itchy vagina and/or discharge 	Speak to your doctor or nurse if you have any of these less serious side effects and they worry you.
 diarrhoea nausea or vomiting pain, redness and swelling where the injection was given 	These are the more common side effects of CEPHAZOLIN VIATRIS. These side effects are usually mild.

Less serious side effects

Serious side effects

Serious side effects	What to do
 Gastrointestinal related: severe abdominal cramps or stomach cramps watery and severe diarrhoea, which may also be bloody Allergic reaction related: skin rash, itching or hives swelling of the face, lips or tongue which may cause difficulty swallowing or breathing chest pain in the context of allergic reactions wheezing or shortness of breath Infection related: fever signs of frequent infections such as fever, chills, sore throat and mouth ulcers 	Call your doctor or nurse straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects. You may need urgent medical attention. These serious side effects are rare

Serious side effects	What to do
Blood related:	
 bleeding or bruising more easily than normal Neurological related: 	
 seizures, changes in mental function, behaviour or state, and/ or muscle jerk 	

After finishing CEPHAZOLIN VIATRIS

Tell your doctor immediately if you notice any of the following side effects, even if they occur several weeks after stopping treatment with CEPHAZOLIN VIATRIS:

- severe abdominal cramps or stomach cramps
- watery and severe diarrhoea, which may also be bloody
- fever, in combination with one or both of the above.

Do not take any diarrhoea medicine without first checking with your doctor.

These are rare but serious side effects. You may have a serious condition affecting your bowel. Therefore, you may need urgent medical attention. However, this side effect is rare.

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 CEPHAZOLIN VIATRIS contains

Active ingredient (main ingredient)	cefazolin sodium 2 g per vial
Other ingredients (inactive ingredients)	nil

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

What CEPHAZOLIN VIATRIS looks like

CEPHAZOLIN VIATRIS is a white to off-white crystalline powder. It is reconstituted before being injected. CEPHAZOLIN VIATRIS is available in packs of 10 vials. (AUST R 154640).

Who distributes CEPHAZOLIN 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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