

# CEFTRIAXONE VIATRIS

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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### 1. Why am I given CEFTRIAXONE VIATRIS?

CEFTRIAXONE VIATRIS contains the active ingredient ceftriaxone sodium. CEFTRIAXONE VIATRIS is an antibiotic used to treat infections in different parts of the body caused by bacteria. For more information, see Section [1. Why am I given CEFTRIAXONE VIATRIS?](#) in the full CMI.

### 2. What should I know before I am given CEFTRIAXONE VIATRIS?

You should not be given CEFTRIAXONE VIATRIS if you have ever had an allergic reaction to ceftriaxone sodium or penicillin.

**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 [2. What should I know before I am given CEFTRIAXONE VIATRIS?](#) in the full CMI.

### **3. What if I am taking other medicines?**

Some medicines and CEFTRIAXONE VIATRIS may interfere with each other.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### **4. How CEFTRIAXONE VIATRIS is given?**

CEFTRIAXONE VIATRIS will be given by either a doctor or nurse. It can be given either as a slow injection into a vein or as an injection into a large muscle. More instructions can be found in Section [4. How CEFTRIAXONE VIATRIS is given?](#) in the full CMI.

### **5. What should I know while I am given CEFTRIAXONE VIATRIS?**

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• If the symptoms of your infection do not improve within a few days or if</li></ul>
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	<p>they become worse, tell your doctor.</p> <ul style="list-style-type: none"> <li>● If you get severe diarrhoea tell your doctor, nurse or pharmacist immediately even if occurs several weeks after CEFTRIAXONE VIATRIS has stopped.</li> <li>● Tell your doctor if you get a sore or white furry mouth or tongue or if you get vaginal itching or discharge. You may have a fungal infection called thrush.</li> </ul>
<p><b>Things you should not do</b></p>	<ul style="list-style-type: none"> <li>● If you have diarrhoea, do not take any medicine to stop the diarrhea without first checking with your doctor. Diarrhea may mean you have a serious condition affecting your bowel.</li> </ul>
<p><b>Driving or using machines</b></p>	<ul style="list-style-type: none"> <li>● Be careful before you drive or use any machines or tools until you know how CEFTRIAXONE</li> </ul>

VIATRIS affects you. CEFTRIAXONE VIATRIS generally does not cause any problems with your ability to drive or operate machinery. However, CEFTRIAXONE VIATRIS may cause dizziness in some people.

For more information, see Section [5. What should I know while I am given CEFTRIAXONE VIATRIS?](#) in the full CMI.

## 6. Are there any side effects?

**Less serious side effects:** oral thrush, vaginal thrush, swelling, pain or tenderness at the injection site, diarrhoea, nausea, vomiting, headache, taste disturbances, fast or irregular heart beat. **Serious side effects:** severe skin rash, itching or hives; red, blistering, peeling or flaking of the skin; swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing; swelling of the hands, feet or ankles; chest pain in the context of allergic reactions; tiredness, headaches, being short of breath when exercising, dizziness, looking pale and yellowing of the skin and/or eyes; severe diarrhoea (that may contain blood and mucous), stomach pain, and fever; reduced ability to think clearly or concentrate, memory loss,

drowsiness, seizures, muscle twitches and personality change.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# CEFTRIAZONE VIATRIS

Active ingredient(s): *ceftriaxone sodium*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using CEFTRIAZONE 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 CEFTRIAZONE VIATRIS.**

**Where to find information in this leaflet:**

- [1. Why am I given CEFTRIAZONE VIATRIS?](#)
- [2. What should I know before I am given CEFTRIAZONE VIATRIS?](#)
- [3. What if I am taking other medicines?](#)
- [4. How CEFTRIAZONE VIATRIS is given?](#)
- [5. What should I know while I am given CEFTRIAZONE VIATRIS?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I given CEFTRIAZONE VIATRIS?

**CEFTRIAZONE VIATRIS contains the active ingredient ceftriaxone sodium.** CEFTRIAZONE VIATRIS belongs to a group of antibiotics called

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cephalosporins. These antibiotics work by killing the bacteria that are causing your infection or by stopping bacteria from growing.

**CEFTRIAZONE VIATRIS is used to treat infections in different parts of the body caused by bacteria.**

**CEFTRIAZONE VIATRIS is also used to prevent infections before, during and after surgery.**

**CEFTRIAZONE VIATRIS will not work against infections caused by viruses such as colds or the flu.**

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

Your doctor may have prescribed CEFTRIAZONE VIATRIS for another reason.

CEFTRIAZONE VIATRIS is not addictive.

## **2. What should I know before I am given CEFTRIAZONE VIATRIS?**

### **Warnings**

**You should not be given CEFTRIAZONE VIATRIS if:**

- you have had an allergic reaction to ceftriaxone, other cephalosporins or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include severe skin rash, itching, hives, dry skin, swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing, swelling of the hands, feet or ankles.

- you have had a serious allergic reaction to penicillins. You may have an increased chance of being allergic to CEFTRIAXONE VIATRIS if you are allergic to penicillins.

**In newborns, CEFTRIAXONE VIATRIS should not be given if they require (or are expected to require) treatment with calcium containing intravenous solutions, including parenteral nutrition (intravenous nutrition).**

**CEFTRIAXONE VIATRIS should not be given to preterm newborns or newborns with certain liver disorders.**

**If you are not sure if you should start using CEFTRIAXONE VIATRIS, contact your doctor.**

**Your doctor must know about all of the following before you are given CEFTRIAXONE VIATRIS.**

**You must tell your doctor if:**

- have any type of allergic reaction to cephalosporins or penicillin medicines. You may have an increased chance of being allergic to CEFTRIAXONE VIATRIS if you are allergic to penicillins.
- you have had an allergy or over-reaction to lidocaine (lignocaine) or other anaesthetic drugs. These substances may be used to dissolve CEFTRIAXONE VIATRIS before administration.



- you are allergic to any other medicines or substances such as foods, preservatives or dyes.
- you have or have ever had any medical conditions including: kidney disease, bowel conditions (e.g. inflammation of the large bowel), diarrhoea associated with previous use of antibiotics or a previous infection of your intestine with a bacteria called *Clostridium difficile*.

If you have not told your doctor about any of the above, tell them before you are given CEFTRIAXONE 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 [6. Are there any side effects?](#)

## **Pregnancy and breastfeeding**

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

Talk to your doctor if you are breastfeeding or intend to breastfeed. Your doctor will discuss the risks and benefits of using CEFTRIAXONE VIATRIS during pregnancy or when breast feeding.

### **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 CEFTRIAZONE VIATRIS or may affect how it works. These include:**

- chloramphenicol (Chloromycetin<sup>®</sup>, Chlorsig<sup>®</sup>).
- fluconazole, a medicine used to treat fungal infections.
- amsacrine, a medicine used to treat cancer.

You may need to take different amounts of your medicine, or you may need to take different medicines altogether. Your doctor will advise you.

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

Some antibiotics may decrease the effectiveness of some birth control pills, although this has not been shown with CEFTRIAZONE VIATRIS.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while being given CEFTRIAZONE 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 CEFTRIAZONE VIATRIS.**

## **4. How CEFTRIAZONE VIATRIS is given?**

**CEFTRIAZONE VIATRIS must only be given by a doctor or nurse.**

CEFTRIAZONE VIATRIS can be given in two ways:

- as a slow injection into a vein, or

- as a deep injection into a large muscle.

**CEFTRIAZONE VIATRIS should not be mixed or administered with calcium-containing solutions, even via different infusion lines.**

Your doctor will decide what dose and how long you will receive CEFTRIAZONE VIATRIS for. This will depend on your infection and other factors, such as your weight. For most infections, CEFTRIAZONE VIATRIS is usually given once a day. The length of treatment is usually 4-14 days.

Sometimes a single dose of CEFTRIAZONE VIATRIS is required for the treatment and prevention of certain infections.

## **If you are given too much CEFTRIAZONE VIATRIS**

As your dose of CEFTRIAZONE 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.

If too much CEFTRIAZONE VIATRIS is given, you may experience symptoms such as skin reactions, chills, diarrhoea, stomach upsets, headache or dizziness.

### **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.

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

## **5. What should I know while I am given CEFTRIAXONE VIATRIS**

### **Things you must 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 CEFTRIAXONE 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 first checking with your doctor.

**If you get a sore or furry white mouth or tongue while using or soon after stopping CEFTRIAXONE 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 CEFTRIAXONE VIATRIS allows fungi to grow, and the above symptoms can

occur. CEFTRIAXONE VIATRIS does not work against fungi.

**If you become pregnant while you are using CEFTRIAXONE VIATRIS, tell your doctor immediately.**

**If you are about to start taking any new medicine, tell your doctor and pharmacist that you are using CEFTRIAXONE VIATRIS.**

**If you have to test your urine for sugar while you are being given CEFTRIAXONE VIATRIS, make sure your doctor knows which type of test you use.**

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

**If you have any blood tests, tell your doctor you are being given CEFTRIAXONE VIATRIS.**

Complete blood counts should be done at regular intervals as CEFTRIAXONE VIATRIS may affect the results of some blood tests.

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

## **Things you should not do**

- **Do not give CEFTRIAXONE VIATRIS to anyone else even if they seem to have the same condition as you.**
- **Do not use CEFTRIAXONE VIATRIS to treat other complaints unless your doctor says to.**

## **Driving or using machines**

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

CEFTRIAXONE VIATRIS generally does not cause any problems with your ability to drive or operate machinery. However, as with many other medicines, CEFTRIAXONE VIATRIS may cause dizziness in some people.

## **Looking after your medicine**

**CEFTRIAXONE VIATRIS will be stored in the pharmacy or on the ward.**

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

The reconstituted solution should be used immediately, but, if necessary, can be kept in a refrigerator between 2 °C and 8 °C for not more than 24 hours after mixing. Do not freeze.

## **6. Are there any side effects?**

### **While you are receiving CEFTRIAXONE VIATRIS**

**Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are receiving CEFTRIAXONE VIATRIS.**

As with all prescription medicines, it is possible that CEFTRIAXONE VIATRIS will cause you to experience some unwanted side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

**Ask your doctor to answer any questions you may have.**

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

You may not experience any of them.

**Less serious side effects**

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"><li>● oral thrush – white, furry, sore tongue and mouth</li><li>● vaginal thrush – sore and itchy vagina sometimes with a white discharge</li><li>● a hard lump, swelling, pain or tenderness at the injection site</li><li>● diarrhoea, feeling sick, vomiting</li><li>● headache or dizziness</li><li>● taste disturbances</li><li>● fast or irregular heart beat.</li></ul>	<p><b>Speak to your doctor or nurse if you have any of these less serious side effects and they worry you.</b></p> <p><b>These side effects are usually mild.</b></p>

## Serious side effects

Serious side effects	What to do
<p data-bbox="204 443 582 488"><b>Allergic reaction</b></p> <ul data-bbox="204 521 778 1238" style="list-style-type: none"><li data-bbox="204 521 778 629">● severe skin rash, itching or hives</li><li data-bbox="204 651 778 759">● red, blistering, peeling or flaking of the skin</li><li data-bbox="204 781 778 1117">● swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing, swelling of the hands, feet or ankles</li><li data-bbox="204 1140 778 1238">● chest pain in the context of allergic reactions</li></ul> <p data-bbox="204 1261 582 1305"><b>Body as a whole</b></p> <ul data-bbox="204 1339 778 1910" style="list-style-type: none"><li data-bbox="204 1339 778 1675">● tiredness, headaches, being short of breath when exercising, dizziness, looking pale and yellowing of the skin and/or eyes</li><li data-bbox="204 1697 778 1910">● severe diarrhoea (that may contain blood and mucous), stomach pain, and fever</li></ul>	<p data-bbox="817 443 1372 835"><b>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.</b></p> <p data-bbox="817 869 1316 969"><b>These side effects are rare.</b></p>



<b>Serious side effects</b>	<b>What to do</b>
<p data-bbox="199 257 582 369"><b>Nervous system disorders</b></p> <ul data-bbox="199 392 774 907" style="list-style-type: none"> <li>• Reduced ability to think clearly or concentrate, memory loss, drowsiness, seizures, muscle twitches and personality change. These symptoms may be related to a condition called encephalopathy.</li> </ul>	

## **After finishing CEFTRIAXONE VIATRIS**

**Tell your doctor immediately if you notice any of the following side effects, even if they occur several weeks after stopping treatment with CEFTRIAXONE 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.

These are rare but serious side effects. You may have a serious condition affecting your bowel. You may need urgent medical attention. However, these side effects are rare.

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

Other possible side effects may include:

- problems with gallbladder and/or liver which may cause pain, nausea, vomiting, yellowing of the skin, itching, unusually dark urine, and clay-coloured stools

Treatment with CEFTRIAXONE VIATRIS, particularly in elderly patients with serious kidney or nervous system problems may rarely cause consciousness, abnormal movements, agitation and convulsions.

Other side effects not listed above may also occur in some patients.

**Tell your doctor if you notice anything else that is making you feel unwell.**

## **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 [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems)

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 CEFTRIAZONE VIATRIS contains

<b>Active ingredient (main ingredient)</b>	Ceftriaxone sodium
<b>Other ingredients (inactive ingredients)</b>	This product contains no other ingredients

**Do not take this medicine if you are allergic to any of ceftriaxone sodium.**

## What CEFTRIAZONE VIATRIS looks like

CEFTRIAZONE VIATRIS is a white to slightly yellow powder, which will be reconstituted before being injected.

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

- CEFTRIAZONE VIATRIS 1000 mg (AUST R 164920)
- CEFTRIAZONE VIATRIS 2000 mg (AUST R 164917)

## Who distributes CEFTRIAZONE VIATRIS

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

[www.viatris.com.au](http://www.viatris.com.au)

Phone: 1800 274 276

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