

**CEFTRIAZONE 0.5 g & 1 g POWDER FOR INJECTION,  
CEFTRIAZONE 2 g POWDER FOR INFUSION**  
*Ceftriaxone sodium*

**DEVATIS**

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## **Consumer Medicine Information (CMI)**

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### **What is in this leaflet**

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Please read this leaflet carefully before you start using CEFTRIAZONE Powder for Injection/Infusion.

This leaflet answers some common questions about CEFTRIAZONE Powder for Injection/Infusion. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given CEFTRIAZONE Powder for Injection/Infusion against the benefits they expect it will have for you.

**If you have any concerns about being given this medicine, talk to your doctor or pharmacist.**

**Keep this leaflet with the medicine.** You may need to read it again.

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### **What CEFTRIAZONE Powder for Injection/Infusion is used for**

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CEFTRIAZONE Powder for Injection/Infusion contains ceftriaxone (as ceftriaxone sodium) as the active ingredient.

CEFTRIAZONE Powder for Injection/Infusion is an antibiotic used to treat infections in different parts of the body caused by bacteria. It is also used to prevent infections before, during and after surgery.

CEFTRIAZONE Powder for Injection/Infusion belongs to a group of antibiotics called cephalosporins. These antibiotics work by killing the bacteria that are causing your infection or by stopping bacteria from growing.

Your doctor may have prescribed CEFTRIAZONE Powder for Injection/Infusion for another reason.

**Ask your doctor if you have any questions about why CEFTRIAZONE Powder for Injection/Infusion has been prescribed for you.**

This medicine is available only with a doctor's prescription.  
There is no evidence that it is addictive.

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### **Before you use CEFTRIAZONE Powder for Injection/Infusion**

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#### ***When you must not use it***

**You must not be given CEFTRIAZONE Powder for Injection/Infusion if you have had an allergic reaction to:**

- any medicine containing ceftriaxone
- any other cephalosporin antibiotic.

**You must not be given CEFTRIAZONE Powder for Injection/Infusion if you have had a serious allergic reaction to penicillin.**

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

**CEFTRIAXONE Powder for Injection/Infusion and calcium-containing IV solutions must not be mixed or co-administered to newborns because of the risk of forming a ceftriaxone-sodium salt.**

**CEFTRIAXONE Powder for Injection/Infusion must not be given to preterm newborns or newborns with certain liver disorders.**

**You must not be given CEFTRIAXONE Powder for Injection/Infusion if the packaging is torn or shows signs of tampering or after the expiry date printed on the pack.**

**If you are not sure whether you should be given CEFTRIAXONE Powder for Injection/Infusion, talk to your doctor.**

### *Before you start to use it*

#### **Tell your doctor if:**

- **you have had an allergy or over-reaction to lidocaine or other anesthetic medicines.**

These substances may be used to dissolve CEFTRIAXONE Powder for Injection/Infusion prior to injection.

- **You have allergies to any other medicines, foods, preservatives or dyes.**
- **You are being treated with calcium-containing IV solutions.**
- **You have or have had any medical conditions, including:**
  - kidney disease
  - stomach or bowel problems
  - liver disease
  - bleeding problems
- **You are pregnant, intend to become pregnant, are breast-feeding or plan to breast feed.**

Your doctor will discuss the benefits and possible risks of being given this medicine during breastfeeding or pregnancy.

**If you have not told your doctor about any of the above, tell them before you start being given CEFTRIAXONE Powder for Injection/Infusion.**

### *Taking other medicines*

**Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking CEFTRIAXONE Powder for Injection/Infusion.**

Some medicines may interfere with CEFTRIAXONE Powder for Injection/Infusion. These include chloramphenicol, a medicine used to treat infections.

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

**Talk to your doctor about the need for an additional method of contraception while using CEFTRIAXONE Powder for Injection/Infusion.**

These medicines may be affected by CEFTRIAXONE Powder for Injection/Infusion, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking CEFTRIAXONE Powder for Injection/Infusion.

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## How to use CEFTRIAXONE Powder for Injection/Infusion

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### *How much to use*

Your doctor will decide what dose and how long you will receive CEFTRIAXONE Powder for Injection/Infusion. This depends on the infection being treated and your response to the treatment.

### *When to use it*

For most infections, it is usually given once or twice a day.

### *How long to use it*

Sometimes, only a single dose of CEFTRIAXONE Powder for Injection/Infusion is required for the treatment and prevention of certain infections. Otherwise, the length of treatment is usually between 4 days and 2 weeks.

### *How it is given*

CEFTRIAXONE Powder for Injection/Infusion is a sterile powder which is dissolved and diluted with suitable sterile fluids.

It is given by:

- direct injection into a vein,
- slow infusion into a vein or
- deep injection into a large muscle.

CEFTRIAXONE Powder for Injection/Infusion must only be prepared and given by a doctor or nurse.

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## While you are using CEFTRIAXONE Powder for Injection/Infusion

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### *Things you must do*

**Tell your doctor if the symptoms of your infection do not improve within a few days or if they become worse.**

**Tell your doctor, pharmacist or nurse immediately if you get severe diarrhea. Do this even if it occurs several weeks after CEFTRIAXONE Powder for Injection/Infusion has been stopped.**

Diarrhea may mean that you have a serious condition affecting your bowel. You may need urgent medical care.

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

**Tell your doctor if you get a sore white mouth or tongue while using or soon after stopping CEFTRIAXONE Powder for Injection/Infusion.**

**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 Powder for Injection/Infusion allows fungi to grow and the above symptoms to occur. CEFTRIAXONE Powder for Injection/Infusion does not work against fungi.

**Tell any other doctors, dentists and pharmacists who are treating you that you are being given CEFTRIAZONE Powder for Injection/Infusion, especially if you are about to be started on any new medicines.**

**Tell your doctor immediately if you become pregnant while you are being given CEFTRIAZONE Powder for Injection/Infusion.**

**If you have to test your urine for sugar while you are being given CEFTRIAZONE Powder for Injection/Infusion, make sure your doctor knows which type of test you use.**  
CEFTRIAZONE Powder for Injection/Infusion may affect the results of these tests.

**Tell your doctor you are being given CEFTRIAZONE Powder for Injection/Infusion if you have to have any blood tests.**  
CEFTRIAZONE Powder for Injection/Infusion may affect the results of some blood tests.

### ***Things you must not do***

Do not give CEFTRIAZONE Powder for Injection/Infusion to anyone else, even if they have the same condition as you.

### ***Things to be careful of***

**Be careful driving or operating machinery until you know how CEFTRIAZONE Powder for Injection/Infusion affects you.**

CEFTRIAZONE Powder for Injection/Infusion may cause dizziness in some people. Make sure you know how you react to it before you drive a car, operate machinery or do anything else that may be dangerous.

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## **In case of overdose**

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### ***If you are given too much (overdose)***

As CEFTRIAZONE Powder for Injection/Infusion is given to you under the supervision of your doctor, it is very unlikely that you will receive too much.

**However, if this is the case, immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much CEFTRIAZONE Powder for Injection/Infusion. Do this even if there are no signs of discomfort or poisoning.**

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## **Side effects**

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**Tell your doctor or nurse as soon as possible if you do not feel well while you are being treated with CEFTRIAZONE Powder for Injection/Infusion.**

This medicine helps most people with infections, but it 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 treatment if you get some of the adverse effects.

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

**Tell your doctor or nurse if you notice any of the following side effects and they worry you:**

- oral thrush – white, furry, sore tongue and mouth
- vaginal thrush – sore and itchy vagina sometimes with a white discharge
- pain or swelling at the injection site

- mild diarrhea
- nausea (feeling sick) or vomiting
- headache or dizziness
- taste disturbances
- fever, sweating
- stomach pain or discomfort
- wind
- indigestion.

**Tell your doctor immediately if you notice any of the following, particularly if they occur several weeks after stopping treatment with CEFTRIAZONE Powder for Injection/Infusion:**

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

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

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

**Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following symptoms:**

- skin rash, itching or hives
- severe peeling or flaking of the skin
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- wheezing or shortness of breath
- swelling of the hands, feet or ankles
- bleeding or bruising more easily than normal
- signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers
- signs of anemia such as tiredness, being short of breath when exercising, looking pale
- yellowing of the skin or eyes
- fast or irregular heart beat
- passing less urine than is normal
- blood in the urine
- severe pain in the stomach which spreads to your back.

These are serious side effects. You may need medical attention. Serious side effects are rare.

**Tell your doctor if you notice anything else that is making you feel unwell, even if you think the problems are not connected with this medicine and are not referred to in this leaflet.**

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

**Do not be alarmed by this list of possible side effects.** You may not experience any of them.

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## **After using CEFTRIAZONE Powder for Injection/Infusion**

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### ***Storage***

CEFTRIAZONE Powder for Injection/Infusion will be stored in the pharmacy or on the ward. The powder

for injection/infusion is kept in a cool dry place, protected from light, where the temperature stays below 25°C.

### ***Disposal***

*Do not use CEFTRIAZONE Powder for Injection/Infusion after the expiry date, which is stated on the packaging.*

If your doctor advises you to stop taking CEFTRIAZONE Powder for Injection/Infusion or the medicine has passed its expiry date, ask your pharmacist how to throw away medicines you no longer use. Do not throw away any medicines via wastewater. These measures will help protect the environment.

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## **Product description**

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### ***What it looks like***

CEFTRIAZONE Powder for Injection/Infusion is almost white or yellowish, crystalline powder in a glass vial with a rubber stopper. The powder is dissolved and diluted with suitable sterile fluids before it is used.

Ceftriaxone (as Ceftriaxone sodium) 0.5 g & 1 g Powder for Injection are presented in 1 vial, 5 vial and 10 vial packs.

Ceftriaxone (as Ceftriaxone sodium) 2 g Powder for Infusion is presented in 1 vial, 5 vial and 10 vial packs.

Not all pack sizes may be currently marketed.

### ***Ingredient***

#### Active ingredient(s):

Each vial contains 0.5 g, 1 g or 2 g of ceftriaxone (as ceftriaxone sodium).

#### Inactive ingredients:

There are no other ingredients.

CEFTRIAZONE Powder for Injection/Infusion does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

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## **Sponsor**

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## **Date of Preparation**

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This leaflet was revised in August 2021.