CEFTRIAXONE 0.5 g & 1 g POWDER FOR INJECTION, CEFTRIAXONE 2 g POWDER FOR INFUSION

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Ceftriaxone sodium

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about CEFTRIAXONE 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 CEFTRIAXONE 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.

What Ceftriaxone Powder for Injection/Infusion is used for

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

CEFTRIAXONE 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.

CEFTRIAXONE 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.

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.

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

There is no evidence that it is addictive.

Before you are given it

When you must not be given it

You must not be given CEFTRIAXONE 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 CEFTRIAXONE 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 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 are given it

Tell vour doctor if:

you have had an allergy or over-reaction to lidocaine or other anaesthetic drugs.

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

Some medicines may be affected by CEFTRIAXONE Powder for Injection/Infusion or may affect how well it works.

These include chloramphenicol, a medicine used to treat infections.

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

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

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

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while being given CEFTRIAXONE Powder for Injection/Infusion.

How it is given

How much is given

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.

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

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.

If you are given too much (overdose)

As CEFTRIAXONE 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 you experience any side effects after being given CEFTRIAXONE Powder for Injection/Infusion, tell your doctor immediately or call the Poisons Information Centre on 13 11 26 (Australia) or 0800 POISON or 0800 764 766 (New Zealand).

While you are being given it

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 diarrhoea. Do this even if it occurs several weeks after CEFTRIAXONE Powder for Injection/Infusion 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.

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 CEFTRIAXONE 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 CEFTRIAXONE Powder for Injection/Infusion.

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

CEFTRIAXONE Powder for Injection/Infusion may affect the results of these tests.

Tell your doctor you are being given CEFTRIAXONE Powder for Injection/Infusion if you have to have any blood tests.

CEFTRIAXONE Powder for Injection may affect the results of some blood tests.

Things to be careful of

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

CEFTRIAXONE Powder for Injection/Infuison 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.

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well while you are being treated with CEFTRIAXONE 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 experience some of the side 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 diarrhoea
- 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 CEFTRIAXONE Powder for Injection/Infusion:

- 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, 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 anaemia 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 side effects not listed above may also occur in some patients.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After using it

Storage

CEFTRIAXONE 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.

Product description

What it looks like

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

Ceftriaxone (Ceftriaxone as 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

Each vial contains 0.5 g, 1 g or 2 g of ceftriaxone (as ceftriaxone sodium). There are no other ingredients.

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

Sponsor

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