Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Ceftriaxone Injection. 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 Injection against the benefits they expect it will have for you. If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet. You may need to read it again.

WHAT CEFTRIAXONE INJECTION IS USED FOR

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

Ceftriaxone Injection is also used to prevent infections before, during and after surgery.

Ceftriaxone Injection will not work against infections caused by viruses such as colds or the flu.

Ceftriaxone Injection 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 Ceftriaxone Injection for another reason.

Ask your doctor if you have any questions why Ceftriaxone Injection has been prescribed for you.

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

Ceftriaxone Injection is not addictive.

BEFORE YOU ARE GIVEN CEFTRIAXONE INJECTION

When you must not be given it

Do not use Ceftriaxone Injection 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 Injection if you are allergic to penicillins.

In newborns, Ceftriaxone Injection and IV calcium-containing solutions must not be given within 48 hours of each other.

Ceftriaxone Injection should not be given to preterm newborns or newborns with certain liver disorders.

If you are not sure if you should start using Ceftriaxone Injection, contact your doctor.

Before you are given it

Your doctor must know about all the following before you are given Ceftriaxone Injection.

You must tell your doctor if:

- You have any type of allergic reaction to penicillin medicines You may have an increased chance of being allergic to Ceftriaxone Injection if you are allergic to penicillins.
- You have had an allergy or over-reaction to lignocaine or other anaesthetic drugs. These substances may be used to dissolve Ceftriaxone Injection before administration.
- You are allergic to any other medicines or any other substances such as foods, preservatives or dyes.
- 4. You have or have ever had any medical conditions including:
- · kidney disease
- bowel conditions, eg. Inflammation of the large bowel.
- You are pregnant, intend to become pregnant, are breast feeding or plan to breast feed. Your doctor will discuss the risks and benefits of using Ceftriaxone Injection during pregnancy or when breastfeeding.

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

TAKING OTHER MEDICINES

Tell your doctor if you are taking any other medicines including any that you have bought from a pharmacy, supermarket or healthfood shop. Some medicines and Ceftriaxone Injection may interfere with each other. These include:

 chloramphenicol, a medicine used to treat infections.

This medicine may be affected by Ceftriaxone Injection, or may affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

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

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

Your doctor and pharmacist have more information on medicines to be careful with or avoid while being given Ceftriaxone Injection.

HOW CEFTRIAXONE INJECTION IS GIVEN

Ceftriaxone Injection is given in two ways:

- as a slow injection into a vein,
- as a deep injection into a large muscle.

Ceftriaxone Injection must only be given by a doctor or nurse.

Ceftriaxone Injection 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 Ceftriaxone Injection.

This depends on your infection and other factors, such as your weight. For most infections, Ceftriaxone Injection is usually

given once a day. The length of treatment usually is 4-14 days.

Sometimes only a single dose of Ceftriaxone Injection is required for the treatment and prevention of certain infections.

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

WHILE YOU ARE USING CEFTRIAXONE INJECTION

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 Injection 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 Injection, tell your doctor.

Also tell your doctor if you get vaginal itching or discharge. This may mean that you have a fungal infection called thrush. Sometimes the use of Ceftriaxone Injection allows fungi to grow and the above symptoms to occur. Ceftriaxone injection does not work against fungi.

If you become pregnant while using Ceftriaxone Injection, tell your doctor.

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

If you have any blood tests tell your doctor you are being given Ceftriaxone Injection. Ceftriaxone Injection may affect the results of some blood tests.

Tell all doctors, dentists and pharmacists who are treating you that you are using Ceftriaxone Injection.

Things you must not do

Do not give Ceftriaxone Injection to anyone else even if they seem to have the same condition as you.

Do not use Ceftriaxone Injection to treat other complaints unless your doctor says to.

Things to be careful of

Be careful driving or operating machinery until you know how Ceftriaxone Injection affects you.

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

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Ceftriaxone Injection.

Ceftriaxone Injection helps most people with infections but it may have unwanted side effects in some people. All medicines can have unwanted 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 or pharmacist to answer any questions you may have.

While using it

Tell your doctor if you notice any of the following and they worry you:

- white, furry, sore tongue and mouth (oral thrush);
- sore and itchy vagina and/or discharge (vaginal thrush);
- a hard lump, swelling, pain or tenderness at the injection site;
- · diarrhoea, feeling sick, vomiting;
- · altered sense of taste;
- headache, dizziness;
- fast or irregular heart beat.

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

- severe skin rash, itching or hives;
- red, peeling or 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;
- tiredness, headaches, being short of breath when exercising, dizziness, looking pale and yellowing of the skin and/or eyes.

These may be serious side effects of Ceftriaxone Injection. You may need urgent medical attention. Serious side effects are

After finishing it

Tell your doctor immediately if you notice any of the following side effects, particularly if they occur several weeks after stopping treatment with Ceftriaxone Injection:

- severe abdominal cramps or stomach cramps
- watery and severe diarrhoea
- raised temperature (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. Therefore, you may need urgent medical attention. However, this side effect is rare.

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

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

Ask your doctor or pharmacist if you don't understand anything in this list.

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

PRODUCT DESCRIPTION

Storage

Ceftriaxone Injection will be stored in the pharmacy or on the ward. The powder for injection is kept in a cool dry place where the temperature stays below 25°C.

What Ceftriaxone Injection looks like

Ceftriaxone Injection is available as a white to yellowish-orange powder. It is packaged in a clear glass vial. It is reconstituted with a suitable fluid before injection into a vein.

Inaredients

Ceftriaxone Injection contains the active ingredient, ceftriaxone as the sodium salt.

Each 250mg Ceftriaxone Injection vial contains 250mg ceftriaxone.

Each 500mg Ceftriaxone Injection vial contains 500mg ceftriaxone.

Each 1 gram Ceftriaxone Injection vial contains 1 gram ceftriaxone.

Ceftriaxone Injection 250mg, 500mg and 1 gram is available in packs of 1, 5 and 10 vials.

SPONSOR

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Australia

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AUSTRALIAN REGISTRATION NUMBERS

Ceftriaxone Injection:

250mg vial: AUST R 104486 500mg vial: AUST R 104488 1 gram vial: AUST R 104489