Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about CEFTRIAXONE ICP.

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 using CEFTRIAXONE ICP against the benefits it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

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

What CEFTRIAXONE ICP is used for

CEFTRIAXONE ICP contains the active ingredient ceftriaxone sodium.

CEFTRIAXONE ICP is an antibiotic used to treat bacterial infections in different parts of the body.

CEFTRIAXONE ICP is also used to prevent infections before, during and after surgery.

CEFTRIAXONE ICP belongs to a group of antibiotics called cephalosporins, which work by killing the bacteria that are causing your infection.

Your doctor may have prescribed CEFTRIAXONE ICP for another reason. Ask your doctor if you have any questions about why CEFTRIAXONE ICP has been prescribed for you.

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

Before you are given CEFTRIAXONE

Do not use CEFTRIAXONE ICP if:

- You have an allergy to ceftriaxone, or any other cephalosporins
 - Some of the symptoms of an allergic reaction may include skin rash, itching or hives, asthma, wheezing, shortness of breath, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing;
- 2. You have had a serious allergic reaction to any penicillins;
- The packaging is tom or shows any signs of tampering;
- The use by date or expiry date printed on the pack has passed. If this medicine is used after the expiry date has passed, it may not work as well.

Before you start to take or are given CEFTRIAXONE ICP you must tell 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 CEFTRIAXONE ICP if you are allergic to any cephalosporins or penicillins;
- You are allergic to lignocaine, which may be mixed with CEFTRIAXONE ICP before intramuscular injection, or other local anaesthetics:
- You have allergies to any other medicines or any other substances, such as foods, preservatives or dyes;

- You are pregnant, or intend to become pregnant. Your doctor will discuss the risks and benefits of using CEFTRIAXONE ICP during pregnancy;
- You are breast-feeding or intend to breastfeed. CEFTRIAXONE ICP passes into breast milk and may affect your baby. Your doctor will discuss the risks and benefits of using it when breast-feeding;
- If you have or have had any medical conditions, including kidney disease, stomach or bowel problems, liver disease or bleeding problems.

If you have not told your doctor(s) about any of the above, tell them before you are given CEFTRIAXONE ICP.

Use in children

Your child's doctor will discuss the risks and benefits of your child using CEFTRIAXONE ICP.

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. Some medicines may interfere with CEFTRIAXONE ICP. These include chloramphenicol.

This medicine may be affected by CEFTRIAXONE ICP, 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.

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 CEFTRIAXONE ICP.

How CEFTRIAXONE ICP is given

CEFTRIAXONE ICP must only be given by a doctor or nurse.

CEFTRIAXONE ICP may be given in two ways:

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

How much will you be given

Your doctor will decide what dose and how long you will receive CEFTRIAXONE ICP. This depends on your condition and whether you are taking any other medicines. For most infections, CEFTRIAXONE ICP is usually given once or twice a day.

The length of treatment is usually between 4 days and 2 weeks.

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

While you are using CEFTRIAXONE ICP

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 ICP 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 white mouth or tongue while using or soon after stopping CEFTRIAXONE ICP, 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 ICP allows fungi to grow and the above symptoms to occur. CEFTRIAXONE ICP does not work against fungi.
- If you become pregnant while you are using CEFTRIAXONE ICP, tell your doctor immediately.
- If you are about to start taking any new medicine, tell your doctor and pharmacist that you are using CEFTRIAXONE ICP.
- If you have to test your urine for sugar while you are being given CEFTRIAXONE ICP, make sure your doctor knows which type of test you use. CEFTRIAXONE ICP may affect the results of some of these tests.
- If you have to have any blood tests, tell your doctor you are being given CEFTRIAXONE ICP. CEFTRIAXONE ICP may affect the results of some blood tests.
- Tell all the doctors, dentists and pharmacists who are treating you that you are using CEFTRIAXONE ICP.

Things you must not do

- Do not give CEFTRIAXONE ICP to anyone else, even if they have the same condition as you.
- Do not use CEFTRIAXONE ICP to treat any other complaints unless your doctor tells you to.

Things to be careful of

- Be careful driving or operating machinery until you know how CEFTRIAXONE ICP affects you.
- CEFTRIAXONE ICP may cause dizziness in some people. Make sure you know how you react to CEFTRIAXONE ICP before you drive a car, operate machinery or do anything else that may be dangerous if you are affected.

Side effects

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are being given CEFTRIAXONE ICP. 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 side effects. Ask your doctor or pharmacist to answer any questions you may have.

While using CEFTRIAXONE ICP tell your doctor or nurse if you notice any of the following 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
- diarrhoea
- nausea (feeling sick) or vomiting
- · headache or dizziness
- · taste disturbances
- fever

These side effects are usually mild.

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

- severe abdominal cramps or stomach cramps
- watery and severe diarrhoea, which may also be bloody
- 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
- · pain when passing urine

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

After using CEFTRIAXONE ICP

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

- · 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, 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 anything else that is making you feel unwell.

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

Storage

CEFTRIAXONE ICP 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.

The reconstituted solution can be kept in a refrigerator between 2 and 8°C for not more than 24 hours after mixing. Do not freeze.

Product description

What it looks like

CEFTRIAXONE ICP is a white to pale yellow crystalline powder in a glass vial or bottle. When reconstituted for injection, the colour of the solution ranges from pale yellow to amber.

Ingredients

The active ingredient in CEFTRIAXONE ICP is ceftriaxone sodium.

Australian Registration Numbers:

- CEFTRIAXONE ICP 500 mg vial: AUST R 114500
- CEFTRIAXONE ICP 1 g vial: AUST R 114501
- CEFTRIAXONE ICP 2 g infusion bottle: AUST R 114502

Manufacturer

CEFTRIAXONE ICP is distributed by the sponsor of the product:

Intensive Care Products Pty Ltd

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