

Scheduling Status:**S4****CEFTRIAXONE 500 & 1 000 IV iPHARMA, Powder and solvent for solution for intravenous injection****CEFTRIAXONE 500 & 1 000 IM iPHARMA, Powder and solvent for solution for intramuscular injection****Ceftriaxone (as ceftriaxone disodium)****Each gram CEFTRIAXONE iPHARMA contains 3,6 mmol sodium****Sugar free****Read all of this leaflet carefully before you are given CEFTRIAXONE iPHARMA**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.

What is in this leaflet

1. What CEFTRIAXONE iPHARMA is and what it is used for
2. What you need to know before you are given CEFTRIAXONE iPHARMA
3. How CEFTRIAXONE iPHARMA is given
4. Possible side effects
5. How to store CEFTRIAXONE iPHARMA
6. Contents of the pack and other information

1. What CEFTRIAXONE iPHARMA is and what it is used for

CEFTRIAXONE iPHARMA is an antibiotic medicine. It works by killing bacteria that cause infections. It belongs to a group of medicines called cephalosporins.

CEFTRIAXONE iPHARMA is used to treat a variety of infections when caused by organisms that are susceptible to ceftriaxone.

CEFTRIAXONE iPHARMA may also be used to prevent infections during surgery.

2. What you need to know before you are given CEFTRIAXONE iPHARMA

CEFTRIAXONE iPHARMA should not be administered to you:

- If you are hypersensitive (allergic) to ceftriaxone or any of the other ingredients of CEFTRIAXONE iPHARMA (listed in section 6).
- If you have had a sudden or severe allergic reaction to penicillin or similar antibiotics (such as cephalosporins, carbapenems or monobactams). The signs include sudden swelling of the throat or face which might make it difficult to breathe or swallow, sudden swelling of the hands, feet and ankles, and a severe rash that develops quickly.

CEFTRIAXONE iPHARMA, reconstituted with lidocaine (lignocaine) should not be given to you as an injection into a muscle:

- If you are allergic to lidocaine (lignocaine) or local anaesthetics.
- Suffer from hypovolaemia (decrease in blood volume resulting from loss of blood, plasma or plasma fluid).
- Have any heart disorders or suffer from low blood pressure (hypotension).
- Have heart rhythm disorders where the heart beats too slow or irregularly, such as heart block, bradycardia or sino-atrial disorder.
- Suffer from a condition called cardiac decompensation, where your heart is not able to maintain efficient circulation.
- Have porphyria (inherited blood disorder that can cause nerve or skin problems).

CEFTRIAXONE iPHARMA should not be administered to your baby:

- If the baby is premature.
- If the baby is newborn (up to 28 days of age) and has certain blood problems or jaundice (yellowing of the skin or the whites of the eyes) or is to be given a product that contains calcium into their vein.

Warnings and precautions

Tell your doctor or healthcare provider before being given CEFTRIAXONE iPHARMA if:

- You experience or have previously experienced a combination of any of the following symptoms: rash, red skin, blistering of the lips, eyes and mouth, skin peeling, high fever, flu-like symptoms, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes (signs of severe skin reactions, see also section 4 "Possible side effects").
- You have recently received or are about to receive medicines that contain calcium.
- You have other illnesses, such as haemolytic anaemia (a reduction in your red blood cells that may make your skin pale yellow and cause weakness or breathlessness).
- You have recently had diarrhoea after having an antibiotic medicine. You have ever had problems with your gut, in particular colitis (inflammation of the bowel).
- You have liver or kidney problems.
- You are on a low sodium diet.

- You are diabetic and need to have your blood glucose level monitored. CEFTRIAXONE iPHARMA may affect certain blood glucose monitoring systems resulting in incorrect blood glucose readings.
- You have gall stones or kidney stones.

Tell your doctor or healthcare provider before being given CEFTRIAXONE iPHARMA as an injection into a muscle if:

- You have heart problems (such as heart failure) or circulation disorders.
- You have severe breathing disorders.
- You have liver or severe kidney disease.
- You suffer from epilepsy (seizures/fits).
- You suffer from myasthenia gravis (neuromuscular disease that causes muscle weakness).
- You are in shock.
- You have inflammation or infection in the area to be injected.

If you need a blood or urine test

If you are given CEFTRIAXONE iPHARMA for a long time, you may need to have regular blood tests. CEFTRIAXONE iPHARMA can affect the results of urine tests for sugar and a blood test known as the Coombs test. If you are having tests:

- Tell the person taking the sample that you have been given CEFTRIAXONE iPHARMA.

Children

Talk to your doctor or pharmacist or nurse before your child is administered CEFTRIAXONE iPHARMA if:

- He/she has recently been given or is to be given a product that contains calcium into their vein.

Other medicines and CEFTRIAXONE iPHARMA

Always tell your healthcare provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

If you are taking any of the following medicines, please consult your healthcare provider:

- A type of antibiotic called an aminoglycoside.
- An antibiotic called chloramphenicol (used to treat infections, particularly of the eyes).
- Oral anticoagulants (used to prevent blood clots).

Consult your healthcare provider if you are having a urine test for sugar and a blood test known as the Coombs' test. See also *"If you need a blood or urine test"*.

Before being given CEFTRIAXONE iPHARMA as an injection into a muscle, consult your healthcare provider if you are taking any of the following medicines:

- Medicines to regulate the rhythm of your heart (e.g. amiodarone and mexiletine).
- Medicines used as muscle relaxants during general anaesthesia (e.g. suxamethonium).
- Medicines for a stomach ulcer (e.g. cimetidine).
- Medicines used to treat high blood pressure or angina (e.g. propranolol, verapamil).
- Antiviral medicines used to treat infections caused by viruses, such as the human immunodeficiency virus (HIV) (e.g. amprenavir, atazanavir, darunavir and lopinavir).
- Medicines to treat certain psychiatric conditions, such as mental illnesses (e.g. pimozide, sertindole, olanzapine, quetiapine, zotepine).
- Medicines to treat nausea and vomiting (e.g. tropisetron, dolasetron).
- Antibiotics used to treat infections (e.g. quinupristin, dalfopristin).
- Diuretic medicines (water tablets) (e.g. hydrochlorothiazide).
- Medicines for epilepsy (e.g. phenytoin), infections (e.g. erythromycin), depression (e.g. fluvoxamine) or glaucoma (e.g. acetazolamide, timolol).
- Medicines for oral contraception (birth control pills) or oral hormone replacement therapy (HRT).
- Opioid medicine used for pain relief (e.g. fentanyl).

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby please consult your doctor, pharmacist or other healthcare provider for advice before being administered CEFTRIAXONE iPHARMA.

Driving and using machines

CEFTRIAXONE iPHARMA can cause dizziness. If you feel dizzy, do not drive or use any tools or machines. Talk to your doctor if you experience these symptoms.

It is not always possible to predict to what extent CEFTRIAXONE iPHARMA may interfere with your daily activities. You should ensure that you do not engage in driving a vehicle or use machines until you are aware of the measure to which CEFTRIAXONE iPHARMA affects you.

3. How to use CEFTRIAXONE iPHARMA

Do not share medicines prescribed for you with any other person.

You will not be expected to give yourself CEFTRIAXONE iPHARMA. It will be given to you by a person who is qualified to do so.

CEFTRIAXONE iPHARMA can be given as

- a drip (intravenous infusion) or as an injection directly into a vein or
- an injection directly into a muscle.

CEFTRIAXONE iPHARMA is made up by the doctor, pharmacist or nurse and will not be mixed with or given to you at the same time as calcium-containing injections.

Your doctor will decide the correct dose of CEFTRIAXONE iPHARMA for you. The dose will depend on the severity and type of infection; whether you are on any other antibiotics; your weight and age; how well your kidneys and liver are working. The number of days or weeks that you are given CEFTRIAXONE iPHARMA depends on what sort of infection you have.

If you use more CEFTRIAXONE iPHARMA than you should

Since a healthcare provider will administer CEFTRIAXONE iPHARMA, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use CEFTRIAXONE iPHARMA

Since a healthcare provider will administer CEFTRIAXONE iPHARMA, it is unlikely that the dose will be missed. Do not receive a double dose to make up for forgotten individual doses.

4. Possible side effects

CEFTRIAXONE iPHARMA can have side effects.

Not all side effects reported for CEFTRIAXONE iPHARMA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving CEFTRIAXONE iPHARMA, please consult your healthcare provider for advice.

If any of the following happens, stop receiving CEFTRIAXONE iPHARMA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to CEFTRIAXONE iPHARMA. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- A severe rash that develops quickly, with blisters or peeling of the skin and possibly blisters in the mouth (Stevens-Johnson syndrome and toxic epidermal necrolysis which are also known as SJS and TEN).
- A combination of any of the following symptoms: widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement (Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS or drug hypersensitivity syndrome).
- Jarisch-Herxheimer reaction which causes fever, chills, headache, muscle pain, and skin rash that is usually self-limiting. This occurs shortly after starting CEFTRIAZONE iPHARMA treatment for infections with spirochete such as Lyme disease.
- Rapid development of white bumps on the skin surrounded by red skin (acute generalised exanthematous pustulosis), purple spots on skin, abnormal sweating or flushing.
- Widespread redness or scaling of the skin (exfoliative dermatitis).
- Light-headedness, numbness of your tongue or ringing in the ears, which you may experience immediately upon receiving CEFTRIAZONE iPHARMA as an injection into a muscle.
- You experience a loss of consciousness or confusion.
- Fits (seizures), twitching or tremors.
- Breathing difficulties (coughing, wheezing, tightness in the chest, shortness of breath), or you stopped breathing for a period.
- Blood disorder, in which too little oxygen is delivered to your cells. Symptoms may include shortness of breath, headache, nausea, rapid heart rate, fatigue, confusion and loss of consciousness.
- Slowing and stopping of your heart, or changes in the rhythm of your heart, such as an irregular heartbeat.
- Hepatotoxicity (fever, nausea, vomiting, yellowing of your eyes and skin).

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

Tell your doctor if you notice any of the following:

Frequent side effects

- abnormalities with your white blood cells (such as a decrease of leucocytes and an increase of eosinophils) and platelets (decrease of thrombocytes)
- inflammation of the large bowel (colon). The signs include diarrhoea, usually with blood and mucus, stomach pain and fever, loose stools
- changes in the results of blood tests for liver functions

Less frequent side effects

- genital fungal infections (for example, thrush)
- a decrease in the number of white blood cells (granulocytopenia)
- reduction in number of red blood cells (anaemia)
- problems with the way your blood clots. The signs may include bruising easily and pain and swelling of your joints
- headache
- difficulty in breathing (bronchospasm)
- nausea or vomiting
- Hives, skin rash and itching
- blood or sugar in your urine
- pain or a burning feeling along the vein where CEFTRIAZONE iPHARMA has been given. Pain where the injection was given
- a high temperature (fever)
- oedema (fluid build-up)
- shivering
- abnormal kidney function test (blood creatinine increased)

Unknown frequency of side effects

- a secondary infection that may not respond to the antibiotic previously prescribed
- form of anaemia where red blood cells are destroyed (haemolytic anaemia)
- severe decrease in white blood cells (agranulocytosis)
- convulsions
- vertigo (spinning sensation), dizziness, light-headedness
- drowsiness, a feeling of nervousness
- a sensation of pins and needles felt in the arms, legs, hands or feet
- blurred or double vision
- ringing in the ears, becoming more sensitive to everyday sounds
- low blood pressure
- inflammation of the pancreas (pancreatitis). The signs include severe pain in the stomach which spreads to your back

- inflammation of the mucus lining of the mouth (stomatitis)
- inflammation of the tongue (glossitis). The signs include swelling, redness and soreness of the tongue
- problems with your gallbladder, which may cause pain, feeling sick and being sick
- a neurological condition that may occur in neonates with severe jaundice (kernicterus)
- kidney problems caused by deposits of calcium ceftriaxone. There may be pain when passing water (urine) or low output of urine
- a false positive result in a Coombs' test (a test for some blood problems)
- a false positive result for galactosaemia (an abnormal build up of the sugar galactose)
- may interfere with some types of blood glucose tests - please check with your doctor

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to the South African Health Products Regulatory Authority (SAHPRA) via the **"6.04 Adverse Drug Reaction Reporting Form"**, found online under SAHPRA's publications. By reporting side effects, you can help provide more information on the safety of CEFTRIAXONE iPHARMA.

5. How to store CEFTRIAXONE iPHARMA

Store all medicine out of reach of children.

Store at or below 30 °C, keep vial, bottle and ampoules in the outer carton in order to protect from light.

Chemical and physical in-use stability of the reconstituted product has been demonstrated for at least 6 hours at or below 25 °C or 24 hours at 2-8 °C.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would not be longer than the times stated above for the chemical and physical in-use stability.

CEFTRIAXONE iPHARMA reconstituted solution is for single use only and any unused contents must be discarded.

Do not throw away any medicines via wastewater.

Return the expired medicine to your pharmacist for safe disposal.

6. Contents of the pack and other information

What CEFTRIAXONE iPHARMA contains

The active ingredient is ceftriaxone (as disodium salt).

There are no other excipients in the vials containing the powder.

CEFTRIAXONE iPHARMA IM solvent (lidocaine (lignocaine)): contain sodium chloride and sodium hydroxide (pH adjuster).

What CEFTRIAXONE iPHARMA looks like and contents of the pack

Intravenous (IV) injection

CEFTRIAXONE 500 IV and 1000 IV iPHARMA: almost white to yellowish crystalline sterile powder filled in a colourless glass vial.

Solvent: clear sterile solution filled in a clear, colourless glass ampoule.

CEFTRIAXONE 500 IV and 1 000 IV iPHARMA are packed into Ph Eur Type II colourless glass vials with pre-sterilised grey rubber stoppers and capsulated with aluminium caps.

Solvent: sterile water for injection is filled in 5 ml type I glass ampoule.

Pack sizes:

CEFTRIAXONE 500 IV iPHARMA: Outer carton containing 1 powder vial and 1 solvent ampoule of 5 ml sterile water for injection.

CEFTRIAXONE 1 000 IV iPHARMA: Outer carton containing 1 powder vial and 2 solvent ampoules of 5 ml sterile water for injection.

Intramuscular (IM) injection

CEFTRIAXONE 500 IM and 1000 IM iPHARMA: almost white to yellowish crystalline sterile powder filled in a colourless glass vial.

Solvent: clear sterile solution filled in an amber glass ampoule.

CEFTRIAXONE 500 IM iPHARMA is packed into Ph Eur Type II colourless glass vials with pre-sterilised grey rubber stoppers and capsulated with aluminium caps.

Solvent: Type (I) amber coloured glass ampoule with 2 ml lidocaine (lignocaine) HCl 1 %.

CEFTRIAXONE 1 000 IM iPHARMA is packed into Ph Eur Type II colourless glass vials with pre-sterilised grey rubber stoppers and capsulated with aluminium caps.

Solvent: Type (I) amber coloured glass ampoule with 3,5 ml lidocaine (lignocaine) HCl 1 %.

Pack sizes:

CEFTRIAXONE 500 IM iPHARMA: Outer carton containing 1 powder vial and 1 solvent ampoule of 2 ml lidocaine (lignocaine) HCl 1 %.

CEFTRIAXONE 1 000 IM iPHARMA: Outer carton containing 1 powder vial and 1 solvent ampoule of 3,5 ml lidocaine (lignocaine) HCl 1 %.

Reconstituted solutions:

Clear, straw yellow colour solutions free from particulate matter.

Holder of Certificate of Registration:

iPharma (Pty) Ltd

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