

PATIENT INFORMATION LEAFLET**SCHEDULING STATUS****S4****CEFTRIAXONE 250 PHARMA-Q sterile powder for injection****CEFTRIAXONE 500 PHARMA-Q sterile powder for injection****CEFTRIAXONE 1000 PHARMA-Q sterile powder for injection****Ceftriaxone (as ceftriaxone sodium)****Sugar free****Read all of this leaflet carefully before you are given CEFTRIAXONE PHARMA-Q**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- CEFTRIAXONE PHARMA-Q has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What CEFTRIAZONE PHARMA-Q is and what it is used for

CEFTRIAZONE PHARMA-Q is an antibiotic given to adults and children (including newborn babies). It works by killing bacteria that cause infections. It belongs to a group of medicines called cephalosporins.

CEFTRIAZONE PHARMA-Q is used to treat infections of

- the brain (meningitis).
- the lungs.
- the middle ear.
- the abdomen and abdominal wall (peritonitis).
- the urinary tract and kidneys.
- bones and joints.
- the skin or soft tissues.
- the blood.
- the heart.

It can be given:

- to treat specific sexually transmitted infections (gonorrhoea and syphilis).
- to treat patients with low white blood cell counts (neutropenia) who have fever due to bacterial infection.
- to treat infections of the chest in adults with chronic bronchitis.
- to treat Lyme disease (caused by tick bites) in adults and children including newborn babies from 15 days of age.
- to prevent infections during surgery.

2. What you need to know before you are given CEFTRIAZONE PHARMA-Q

CEFTRIAZONE PHARMA-Q should not be administered to you:

- if you are hypersensitive (allergic) to ceftriaxone or any of the other ingredients of CEFTRIAZONE PHARMA-Q (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 breath or swallow, sudden swelling of the hands, feet and ankles, chest pain and a severe rash that develops quickly.
- If you are allergic to lidocaine and you are to be given CEFTRIAZONE PHARMA-Q as an injection into a muscle.

CEFTRIAZONE PHARMA-Q must not be given to babies:

- 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 health care provider before being given the injection:

Special care should be taken with CEFTRIAZONE PHARMA-Q:

- if you have recently received or are about to receive products that contain calcium.
- if 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).
- if you have liver or kidney problems (see section 4).
- if you have gall stones or kidney stones

- if 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).
- if you are on a low sodium diet.
- 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”).

If you need a blood or urine test

If you are given CEFTRIAZONE PHARMA-Q for a long time, you may need to have regular blood tests. CEFTRIAZONE PHARMA-Q 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 CEFTRIAZONE PHARMA-Q.

If you are diabetic or need to have your blood glucose level monitored you should not use certain blood glucose monitoring systems which may estimate blood glucose incorrectly while you are receiving ceftriaxone. If you use such systems check the instructions for use and tell your doctor, pharmacist or nurse. Alternative testing methods should be used if necessary.

Children

Talk to your doctor or pharmacist or nurse before your child is administered CEFTRIAZONE PHARMA-Q:

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

Other medicines and CEFTRIAZONE PHARMA-Q

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

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

Pregnancy and breastfeeding

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 health care provider for advice before receiving CEFTRIAZONE PHARMA-Q.

The doctor will consider the benefit of treating you with CEFTRIAZONE PHARMA-Q against the risk to your baby. The safe use of CEFTRIAZONE PHARMA-Q during pregnancy and breastfeeding has not been established.

Driving and using machines

It is not always possible to predict to what extent CEFTRIAZONE PHARMA-Q may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which CEFTRIAZONE PHARMA-Q affects them.

CEFTRIAZONE PHARMA-Q 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.

CEFTRIAZONE PHARMA-Q contains sodium

CEFTRIAZONE 250 PHARMA-Q sterile powder for injection contains 48,42 mg sodium per vial.

CEFTRIAXONE 500 PHARMA-Q sterile powder for injection contains 96,85 mg sodium per vial.

CEFTRIAXONE 1000 PHARMA-Q sterile powder for injection contains 193,70 mg sodium per vial.

3. How CEFTRIAXONE PHARMA-Q is given

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

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

CEFTRIAXONE PHARMA-Q is usually given by a doctor or nurse. It can be given as

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

CEFTRIAXONE PHARMA-Q 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.

The usual dose

Your doctor will decide the correct dose of CEFTRIAXONE PHARMA-Q 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 PHARMA-Q depends on what sort of infection you have.

People with liver and kidney problems

You may be given a different dose to the usual dose. Your doctor will decide how much CEFTRIAXONE PHARMA-Q you will need and will check you closely depending on the severity of the liver and kidney disease.

Your doctor will tell you how long your treatment with CEFTRIAZONE PHARMA-Q will last.

If you have the impression that the effect of CEFTRIAZONE PHARMA-Q is too strong or too weak, tell your doctor or pharmacist.

If you are given CEFTRIAZONE PHARMA-Q than you should

Since a health care provider will administer CEFTRIAZONE PHARMA-Q, he/ she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use CEFTRIAZONE PHARMA-Q

Since a health care provider will administer CEFTRIAZONE PHARMA-Q, it is unlikely that the dose will be missed.

4. Possible side effects

CEFTRIAZONE PHARMA-Q can have side effects.

Not all side effects reported for CEFTRIAZONE PHARMA-Q are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while using CEFTRIAZONE PHARMA-Q, please consult your health care provider for advice.

If any of the following happens, stop receiving CEFTRIAZONE PHARMA-Q and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Sudden swelling of the face, throat, lips or mouth. This can make it difficult to breathe or swallow.
- Sudden swelling of the hands, feet and ankles.
- Chest pain in the context of allergic reactions, which may be a symptom of allergy triggered cardiac infarction (Kounis syndrome).

These are all very serious side effects. If you have them, you may have had a serious reaction to CEFTRIAXONE PHARMA-Q. 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 CEFTRIAXONE PHARMA-Q treatment for infections with spirochete such as Lyme disease.

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

Tell your doctor if you notice any of the following:

Frequent

- Abnormalities with your white blood cells (such as a decrease of leucocytes and an increase of eosinophils) and platelets (decrease of thrombocytes).
- Loose stools or diarrhoea.
- Changes in the results of blood tests for liver functions.
- Rash.

Less frequent

- Fungal infections (for example, thrush or genital fungal infections).

- 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.
- Dizziness.
- Feeling sick or being sick.
- Pruritis (itching).
- Pain or a burning feeling where CEFTRIAZONE PHARMA-Q has been given. Blisters, bruising, deep redness or rash, irritation, itching, hardening of the skin or swelling at the injection site.
- A high temperature (fever).
- Abnormal kidney function test (blood creatinine increased).
- Inflammation of the large bowel (colon). The signs include diarrhoea, usually with blood and mucus, stomach pain and fever.
- Difficulty in breathing (bronchospasm).
- A lumpy rash (hives) that may cover a lot of your body, feeling itchy and swelling.
- Blood or sugar in your urine.
- Oedema (fluid build-up).
- Shivering.
- Infection at the site of injection.

Frequency unknown

- 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).
- 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 and/or liver which may cause pain, nausea, vomiting, yellowing of the skin, itching, unusually dark urine and clay coloured stools.
- 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.
- Rash with blisters arranged in a circle with central crusting or like a string of pearls (linear IgA disease)
- 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).
- CEFTRIAXONE PHARMA-Q 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 SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of CEFTRIAXONE PHARMA-Q.

5. How to store CEFTRIAZONE PHARMA-Q

Store all medicines out of reach of children.

- Store at or below 25 °C. Protect from light.
- Do not use after the expiry date stated on the label / carton / bottle

Chemical and physical in-use stability of the reconstituted product has been demonstrated for at least 6 hours at room temperature or 24 hours in the refrigerator.

The product is for single use only; any unused portion must be discarded.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What CEFTRIAZONE PHARMA-Q contains

- The active substance is ceftriaxone.

Each vial contains ceftriaxone 250 mg, 500 mg or 1 000 mg (in the form of the disodium salt).

What CEFTRIAZONE PHARMA-Q looks like and contents of the pack

Sterile, white to off-white crystalline, hygroscopic powder. The reconstituted solution is a pale-yellow solution free of visible particles.

CEFTRIAZONE 250 PHARMA-Q: 10 ml clear, colourless glass vials. One vial per outer carton.

CEFTRIAZONE 500 PHARMA-Q: 10 ml clear, colourless glass vials. One vial per outer carton.

CEFTRIAZONE 1 000 PHARMA-Q: 10 ml clear, colourless glass vials. One vial per outer carton.

Holder of Certificate of Registration

Pharma-Q (Pty) Ltd

50 Commando Road

Industria West 2003

Johannesburg

South Africa

info@pharmaq.co.za

Tel: 011 247 1600

This leaflet was last revised in

8 August 2025

Registration numbers

CEFTRIAXONE 250 PHARMA-Q: 37/20.1.1/0046

CEFTRIAXONE 500 PHARMA-Q: 37/20.1.1/0048

CEFTRIAXONE 1 000 PHARMA-Q: 37/20.1.1/0049

Access to the corresponding Professional Information

<https://www.pharmaq.co.za>