

Approved Patient Information Leaflet for Medicines for Human Use:

AUSTELL CEFTRIAXONE 1 g

SCHEDULING STATUS: S4

AUSTELL CEFTRIAXONE 1 g Powder for Injection

Ceftriaxone sodium

Read all of this leaflet carefully before you are given AUSTELL CEFTRIAXONE

- 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.

What is in this leaflet

1. What AUSTELL CEFTRIAXONE is and what it is used for
2. What you need to know before you are given AUSTELL CEFTRIAXONE
3. How to be given AUSTELL CEFTRIAXONE
4. Possible side effects
5. How to store AUSTELL CEFTRIAXONE
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1. What AUSTELL CEFTRIAXONE is and what it is used for

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

AUSTELL CEFTRIAXONE is indicated for:

- Sepsis
- Meningitis in neonates, infants
- Stomach infections (peritonitis, infections of the biliary tract)
- Infections of the bone, joints, soft tissue, skin and of wounds
- Kidney and urinary tract infections
- Lung infections, particularly pneumonia, and ear, nose and throat infections.
- Uncomplicated gonorrhoea.

2. What you need to know before you are given AUSTELL CEFTRIAZONE

You must not be given AUSTELL CEFTRIAZONE

- if you are hypersensitive (allergic) to ceftriazone or cephalosporins.
- if you are hypersensitive (allergic) to penicillin's.

AUSTELL CEFTRIAZONE 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 AUSTELL CEFTRIAZONE injection:

- 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.
- if 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 AUSTELL CEFTRIAXONE for a long time, you may need to have regular blood tests. AUSTELL CEFTRIAXONE 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 AUSTELL CEFTRIAXONE.

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

Other medicines and AUSTELL CEFTRIAXONE

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

AUSTELL CEFTRIAXONE can affect or be affected by other medicines you are taking. Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. This is particularly important if you are:

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

Pregnancy and 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 health care provider for advice before taking this medicine.

Driving and using machines

It is not always possible to predict to what extent AUSTELL CEFTRIAXONE 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 AUSTELL CEFTRIAXONE affects them.

3. How AUSTELL CEFTRIAXONE is given

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

AUSTELL CEFTRIAXONE will be given to you as an injection or infusion into a large vein or into a muscle.

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

AUSTELL CEFTRIAXONE 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 AUSTELL CEFTRIAXONE 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 AUSTELL CEFTRIAXONE depends on what sort of infection you have.

Adults and children over 12 years

- 1 to 2 g once a day depending on the severity and type of infection. If you have a severe infection, your doctor will give you a higher dose (up to 4 g once a day).

Newborn babies (0 - 14 days)

- 20 - 50 mg AUSTELL CEFTRIAXONE for each kg of the child's body weight once a day depending on the severity and type of infection.
- The maximum daily dose is not to be more than 50 mg for each kg of the baby's weight.

Infants and children (15 days to 12 years)

- 20 – 80 mg AUSTELL CEFTRIAXONE for each kg of the child's body weight once a day depending on the severity and type of infection.
- If you have a severe infection, your doctor will give you a higher dose up to 100 mg for each kg of body weight to a maximum of 4 g once a day. If your daily dose is higher than 2 g, you may receive it as a single dose once a day or as two separate doses.
- Children with a body weight of 50 kg or more should be given the usual adult dose.

If you are given more AUSTELL CEFTRIAXONE than you should

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

If you forget to use AUSTELL CEFTRIAZONE

Since a health care provider will administer AUSTELL CEFTRIAZONE, it is unlikely that the dose will be missed. Do not take a double dose (two injections at the same time) to make up for a missed dose.

If you stop taking AUSTELL CEFTRIAZONE

Do not stop taking AUSTELL CEFTRIAZONE unless your doctor tells you to. If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects

AUSTELL CEFTRIAZONE can have side effects.

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

If any of the following happens, stop taking AUSTELL CEFTRIAZONE 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 very serious side effects. If you have them, you may have had a serious reaction to AUSTELL CEFTRIAZONE. 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 AUSTELL CEFTRIAXONE 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 side effects:

- 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 side effects:

- 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.
- Dizziness.
- Feeling sick or being sick.
- Pruritis (itching).
- Pain or a burning feeling along the vein where AUSTELL CEFTRIAXONE has been given.
Pain where the injection was given.
- 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.

Side effects with 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, 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).
- AUSTELL CEFTRIAXONE 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 or pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of AUSTELL CEFTRIAXONE.

5. How to store AUSTELL CEFTRIAXONE

Store all medicines out of reach of children.

Your doctor, pharmacist or healthcare professional knows how to store AUSTELL CEFTRIAXONE. The doctor or nurse who is administering AUSTELL CEFTRIAXONE to you, will make sure that the medicine is not used after the expiry date printed on the vial.

Store at or below 25 °C.

Protect from light.

Reconstituted product should be stored in original vials at least 6 hours at or below 25 °C in daylight, or 24 hours at 2 – 8 °C.

6. Contents of the pack and other information

What AUSTELL CEFTRIAXONE contains

- The active substance is Ceftriaxone sodium.
- There are no other ingredients.

What AUSTELL CEFTRIAZONE looks like and contents of the pack

AUSTELL CEFTRIAZONE is supplied 10 mL Colourless glass vials packed into a cardboard carton.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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