

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

Sandoz® Ceftriaxone 0,5 g (powder for solution for injection)

Sandoz® Ceftriaxone 1,0 g (powder for solution for injection)

Sandoz® Ceftriaxone 2,0 g (powder for solution for injection)

Ceftriaxone

Sugar free

Read all of this leaflet carefully before you receive SANDOZ CEFTRIAXONE.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, your pharmacist, nurse, or other health care provider.
- SANDOZ CEFTRIAXONE 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 SANDOZ CEFTRIAXONE is and what it is used for
2. What you need to know before you use SANDOZ CEFTRIAXONE
3. How to receive SANDOZ CEFTRIAXONE
4. Possible side effects
5. How to store SANDOZ CEFTRIAXONE
6. Contents of the pack and other information

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

SANDOZ CEFTRIAXONE is an antibiotic used to treat infections in different parts of the body, caused by bacteria.

Ceftriaxone is also used to prevent infections following surgery.

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

Ceftriaxone belongs to a group of antibiotics called cephalosporins. These antibiotics work by killing the bacteria that are causing your infection.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

2. What you need to know before you use SANDOZ CEFTRIAXONE

SANDOZ CEFTRIAXONE should not be administered to you:

- If you are hypersensitive to ceftriaxone, other cephalosporins or any of the ingredients of SANDOZ CEFTRIAXONE (listed in section 6).
- If you have had a serious allergic reaction to any penicillins or similar antibiotics (such as cephalosporins, carbapenems or monobactams). Some of the symptoms of an allergic reaction may include asthma, wheezing, shortness of breath, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, skin rash, itching or hives.
- If you are allergic to lidocaine, SANDOZ CEFTRIAXONE should be given as an injection into a muscle.
- If you are not sure whether you should be given SANDOZ CEFTRIAXONE, tell your doctor, nurse or pharmacist.

SANDOZ CEFTRIAXONE must not be given to babies if:

- The baby is premature.

- 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:

- If you have had any type of allergic reaction to any cephalosporin or penicillin medicines (symptoms may include: rash, red skin, blistering of the lips, eyes and mouth, skin peeling, high fever, flu-like symptoms).
- If you have recently received or are about to receive products that contain calcium.
- If you have liver or kidney problems.
- If you have gallstones 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 have a disease of the brain (symptoms include: decreased level of consciousness, altered mental state, sudden involuntary (unintended) jerking of a muscle or group of muscles and fits).
- If you are allergic to lignocaine or other local anaesthetics. Lignocaine can be mixed with SANDOZ CEFTRIAXONE prior to injection.
- *If you have allergies to:*
 - any other medicines.
 - any other substances, such as foods, preservatives or dyes.
- *If you have, or have had any medical conditions, including:*
 - kidney disease.
 - stomach or bowel problems.
 - liver disease.
 - bleeding problems.

Diarrhoea:

If you get severe diarrhoea tell your doctor, pharmacist or nurse immediately. Do this even if it occurs several weeks after SANDOZ CEFTRIAXONE has been stopped. Do not take any diarrhoea medicine without first checking with your doctor. Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care.

Fungal infections:

If you get a sore white mouth or tongue while being given or soon after stopping SANDOZ CEFTRIAXONE, tell your doctor or pharmacist. Also, tell your doctor or pharmacist if you get vaginal itching or discharge. This may mean you have a fungal infection called thrush. Sometimes the use of ceftriaxone allows fungi to grow and the above symptoms to occur. SANDOZ CEFTRIAXONE does not work against fungi.

Laboratory tests:

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

If you have to have any blood tests, tell your doctor you are being given this medicine. SANDOZ CEFTRIAXONE may affect the results of some blood tests.

Other medicines and SANDOZ CEFTRIAXONE

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

If you are about to start taking any new medicine, remind your doctor and pharmacist that you are being given SANDOZ CEFTRIAXONE.

Tell any other doctors, dentists or pharmacists who treat you that you are using SANDOZ CEFTRIAXONE.

Tell your doctor or health care provider if you are taking any of the following medicines:

- Aminoglycosides (antibiotic used to treat bacterial infections).
- Calcium containing products.
- Anticoagulants (medicines used to treat blood clots).
- Diuretics (also called water pills, are medications used to help the kidneys get rid of salt and water by increasing the amount of urine produced).
- Chloramphenicol (used to treat infections, particularly of the eyes).
- Hormonal contraceptives (used for the prevention of pregnancy).

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 taking SANDOZ CEFTRIAXONE.

If you are pregnant:

SANDOZ CEFTRIAXONE may affect your developing baby if you use it during pregnancy. Your doctor will discuss the risks and benefits of using SANDOZ CEFTRIAXONE during pregnancy.

If you are breastfeeding or intend to breastfeed:

SANDOZ CEFTRIAXONE passes into breast milk and may affect your baby. Your doctor will discuss the risks and benefits of using it when breastfeeding.

Driving and using machines

SANDOZ CEFTRIAXONE may cause dizziness in some people.

It is not always possible to predict to what extent SANDOZ 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 SANDOZ CEFTRIAXONE affects them. If you feel dizzy after receiving SANDOZ CEFTRIAXONE, do not drive or use machines until you feel better.

3. How to receive SANDOZ CEFTRIAXONE

SANDOZ CEFTRIAXONE must only be given by a doctor or nurse. You will not be expected to give yourself SANDOZ CEFTRIAXONE. It will be given to you by a person who is qualified to do so.

SANDOZ CEFTRIAXONE can be given in two ways:

- As a slow injection into a vein.
- As a deep injection into a large muscle.

Your doctor will decide what dose and how long you will receive SANDOZ CEFTRIAXONE. This depends on your condition and whether you are taking any other medicines. For most infections, SANDOZ CEFTRIAXONE is usually given once a day. If you have the impression that the effect of SANDOZ CEFTRIAXONE is too strong or too weak, talk to your doctor or pharmacist.

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

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

If you have received more SANDOZ CEFTRIAXONE than you should:

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

If you forget to use SANDOZ CEFTRIAXONE:

Since a health care provider will administer SANDOZ CEFTRIAXONE, it is unlikely that the dose will be missed.

4. Possible side effects

SANDOZ CEFTRIAXONE can have side effects.

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

If any of the following happens, stop using SANDOZ CEFTRIAXONE 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.
- 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).

These are all very serious side effects. If you have them, you may have had a serious reaction to SANDOZ CEFTRIAXONE. 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 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 SANDOZ CEFTRIAXONE treatment for infections with spirochetes such as Lyme disease.
- Fits (seizures).
- Difficulty breathing.

- Less urine than is normal for you or kidney stones.
- A neurological condition that may occur in new-borns with severe jaundice (kernicterus).
- Liver disease with nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems.

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:

- Irregularities 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.
- Rash.

Less frequent side effects:

- Secondary infection due to taking antibiotics, fungal infections (for example, thrush).
- Watery and severe diarrhoea, which may also be bloody.
- A decrease in the number of white blood cells (granulocytopenia).
- Anaemia (symptoms include tiredness, headaches, being short of breath when exercising, dizziness and looking pale).
- Problems with the way your blood clots. The signs may include bruising easily and pain and swelling of your joints.
- Headache.
- Dizziness.
- Sudden involuntary (unintended) jerking of a muscle or group of muscles.
- Nausea or vomiting.
- Itching or swelling of the skin.

- Swelling or clotting in the veins.
- Blood or glucose (sugar) in your urine.
- Pain at injection site.
- High temperature, chills.
- Fever, shivering, irregular kidney function test.

Unknown frequency side effects:

- Form of anaemia, illness resulting from the destruction of red blood cells (haemolytic anaemia).
- Severe decrease in white blood cells (agranulocytosis).
- Spinning sensation (vertigo).
- Inflammation of the pancreas, mouth or tongue.
- Problems with your gallbladder (gallstones), which may cause pain or feeling sick.
- 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).
- SANDOZ 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. 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 SANDOZ CEFTRIAXONE.

Suspected adverse reactions can also be reported directly to the HCR via patientsafety.sacg@novartis.com.

5. How to store SANDOZ CEFTRIAXONE

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 25 °C in the outer carton to protect the medicine from light.

The reconstituted solution is intended for immediate use, but the solution may be stored in the original vials in the refrigerator at 2 °C to 8 °C for 48 hours or below 25 °C for 24 hours.

After use, discard any remaining solution.

Do not use SANDOZ CEFTRIAXONE if you notice:

- The packaging is torn or shows signs of tampering.
- The expiry date on the pack has passed.

Return all unused medicines to your pharmacist.

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

6. Contents of the pack and other information

What SANDOZ CEFTRIAXONE contains

SANDOZ CEFTRIAXONE 0,5 g:

Each vial contains dry, sterile ceftriaxone sodium equivalent to 0,5 g ceftriaxone.

SANDOZ CEFTRIAXONE 1,0 g:

Each vial contains dry, sterile ceftriaxone sodium equivalent to 1,0 g ceftriaxone.

SANDOZ CEFTRIAXONE 2,0 g:

Each vial contains dry, sterile ceftriaxone sodium equivalent to 2,0 g ceftriaxone.

What SANDOZ CEFTRIAXONE looks like and contents of the pack

SANDOZ CEFTRIAXONE 0,5 g powder for solution for injection:

White to light-yellow powder in a 15 ml injection vial made of colourless glass, with a rubber stopper and aluminium cap with a colourless flip-off plastic cap.

SANDOZ CEFTRIAXONE 1,0 g powder for solution for injection:

White to light-yellow powder in a 15 ml injection vial made of colourless glass, with a rubber stopper and aluminium cap with a colourless flip-off plastic cap.

SANDOZ CEFTRIAXONE 2,0 g powder for solution for injection:

White to light-yellow powder in a 30 ml injection vial made of colourless glass, with a rubber stopper and aluminium cap with a colourless flip-off plastic cap.

On reconstitution, a yellowish to brown-yellow clear solution is obtained.

Packs for IM, IV injection or for IV infusion containing:

SANDOZ CEFTRIAXONE 0,5 g, 1,0 g and 2,0 g powder for solution for injection is packed in cartons containing 1 or 10 single dose colourless glass vial/s with a rubber stopper and aluminium cap with a colourless flip-off plastic cap.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd¹

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2090

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SANDOZ CEFTRIAXONE 1,0 g: 41/20.1.1/0867

SANDOZ CEFTRIAXONE 2,0 g: 41/20.1.1/0868

Access to the corresponding Professional Information

Not applicable

¹Company Reg. No.: 1990/001979/07