Package leaflet: Information for the patient

Ceftriaxon Sandoz® 0,5, poeder voor oplossing voor injectie 0,5 g
Ceftriaxon Sandoz® 1, poeder voor oplossing voor injectie/infusie 1 g
Ceftriaxon Sandoz® 2, poeder voor oplossing voor injectie/infusie 2 g
ceftriaxone

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [Nationally completed name] is and what it is used for

[Nationally completed name] 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.

[Nationally completed name] 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 [Nationally completed name]

You must not be given [Nationally completed name] if:
- You are allergic to ceftriaxone or any of the other ingredients of this medicine (listed in section 6).
- 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, and a severe rash that develops quickly.
- You are allergic to lidocaine and you are to be given [Nationally completed name] as an injection into a muscle.

[Nationally completed name] 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
Talk to your doctor or pharmacist or nurse before you are given [Nationally completed name] if:
- You have recently received or are about to receive products that contain calcium.
- 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 (see section 4).
- You have gall stones or kidney stones
- 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 are on a low sodium diet.
- 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 [Nationally completed name] for a long time, you may need to have regular blood tests. [Nationally completed name] 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 [Nationally completed name].

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 [Nationally completed name] if:
- He/She has recently been given or is to be given a product that contains calcium into their vein.

Other medicines and [Nationally completed name]
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 breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

The doctor will consider the benefit of treating you with [Nationally completed name] against the risk to your baby.

Driving and using machines
[Nationally completed name] 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.

[Nationally completed name] contains sodium
0.25 g powder for solution for injection:
This medicine contains less than 1 mmol (23 mg) sodium per vial, that is to say essentially 'sodium-free'.

0.5 g powder for solution for injection:
This medicine contains 42 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 2.1% of the recommended maximum daily dietary intake of sodium for an adult.

1 g powder for solution for injection:
This medicine contains 83 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 4.2% of the recommended maximum daily dietary intake of sodium for an adult.

1 g powder for solution for injection/infusion:
This medicine contains 83 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 4.2% of the recommended maximum daily dietary intake of sodium for an adult.

3. How [Nationally completed name] is given

[Nationally completed name] 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. [Nationally completed name] 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 [Nationally completed name] 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 [Nationally completed name] depends on what sort of infection you have.

Adults, older people and children aged 12 years and over with a body weight greater than or equal to 50 kilograms (kg):
- 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). 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.

Newborn babies, infants and children aged 15 days to 12 years with a body weight of less than 50 kg:
- 50-80 mg [Nationally completed name] 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.

Newborn babies (0-14 days)
- 20 – 50 mg [Nationally completed name] 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.

People with liver and kidney problems
You may be given a different dose to the usual dose. Your doctor will decide how much [Nationally completed name] you
will need and will check you closely depending on the severity of the liver and kidney disease.

If you are given more [Nationally completed name] than you should
If you accidentally receive more than your prescribed dose, contact your doctor or nearest hospital straight away.

If you forget to use [Nationally completed name]
If you miss an injection, you should have it as soon as possible. However, if it is almost time for your next injection, skip the missed injection. Do not take a double dose (two injections at the same time) to
make up for a missed dose.

If you stop using [Nationally completed name]

Do not stop taking [Nationally completed name] 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

Like all medicines, this medicine can cause side effects, although not everybody gets them.
The following side effects may happen with this medicine:

Severe allergic reactions (not known, frequency cannot be estimated from the available data)
If you have a severe allergic reaction, tell a doctor straight away.
The signs may include:
- 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.

Severe skin reactions (not known, frequency cannot be estimated from the available data)
If you get a severe skin reaction, tell a doctor straight away.
The signs may include:
- 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 cetriaxone treatment for infections with spirochete such as Lyme disease.

Other possible side effects:

Common (may affect up to 1 in 10 people)
- 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.

Uncommon (may affect up to 1 in 100 people)
- 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 [Nationally completed name] has been given. Pain where the injection was given.
- A high temperature (fever).
- Abnormal kidney function test (blood creatinine increased).

Rare (may affect up to 1 in 1,000 people)
- 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.
- Treatment with ceftriaxone, particularly in elderly patients with serious kidney or nervous system problems may rarely cause decreased consciousness, abnormal movements, agitation and convulsions.

Not known (Frequency cannot be estimated from the available data)
- 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.
- 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).
- [Nationally completed name] may interfere with some types of blood glucose tests - please check with your doctor.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store [nationally completed name]

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and label after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions.
Store in the original package in order to protect from light.

Reconstituted solution:
Once the powder has been dissolved; the solution should be used immediately or stored in a refrigerator at 2-8°C and discarded after 24 hours.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What [nationally completed name] contains

[Nationally completed name] 0.25 g powder and solvent for solution for injection
Powder: The active substance is ceftriaxone.
Each vial contains 0.25 g ceftriaxone (as ceftriaxone disodium, hydrated)
Each lidocaine hydrochloride ampoule contains: 1% (20 mg/2 ml) lidocaine hydrochloride, water for injection, sodium hydrogen carbonate

[Nationally completed name] 0.5 g powder and solvent for solution for injection:
Powder: The active substance is ceftriaxone
Each vial contains: 0.5 g ceftriaxone (as ceftriaxone disodium, hydrated)
Each lidocaine hydrochloride ampoule contains: 1% (20 mg/2 ml) lidocaine hydrochloride, water for injection, sodium hydrogen carbonate

[Nationally completed name] 1 g powder and solvent for solution for injection:
Powder: The active substance is ceftriaxone
Each vial contains: 1 g ceftriaxone (as ceftriaxone disodium, hydrated)
Each lidocaine hydrochloride ampoule contains: 1% (35 mg/3.5 ml) lidocaine hydrochloride, water for injection, sodium hydrogen carbonate

[Nationally completed name] 1 g powder and solvent for solution for injection/infusion:
Powder: The active substance is ceftriaxone
Each vial contains: 1 g ceftriaxone (as ceftriaxone disodium, hydrated)
Each ampoule contains: 10 ml water for injection as a solvent

What [nationally approved name] looks like and contents of the pack

Powder and solvent for solution for injection/infusion.

The powder is coloured white to yellowish.
The solvent is a clear and colourless solution.

Pack sizes:
1 vial + 1 ampoule
10 vials + 10 ampoules *(only for strength 004, 005, 006)*

Not all pack sizes may be marketed

Houder van de vergunning voor het in de handel brengen en fabrikant

Houder van de vergunning voor het in de handel brengen
Sandoz B.V., Veluwezoom 22, 1327 AH Almere, Nederland

Fabrikant
Sandoz GmbH
Biochemiestraβe 10
6250 Kundl
Oostenrijk

In het register ingeschreven onder:
Ceftriaxon Sandoz® 0,5, poeder voor oplossing voor injectie 0,5 g is in het register ingeschreven onder RVG 26049
Ceftriaxon Sandoz® 1, poeder voor oplossing voor injectie/infusie 1 g is in het register ingeschreven onder RVG 26050
Ceftriaxon Sandoz® 2, poeder voor oplossing voor injectie/infusie 2 g is in het register ingeschreven onder RVG 26051

Dit geneesmiddel is geregistreerd in lidstaten van de EEA onder de volgende namen:

Oostenrijk:	Ceftriaxon “Sandoz” 0.5 g – Pulver zur Herstellung einer Injektionslosung
	Ceftriaxon “Sandoz” 1 g - – Pulver zur Herstellung einer Injektionslosung
	Ceftriaxon “Sandoz” 2 g - – Pulver zur Herstellung einer Injektionslosung
België:	Ceftriaxone Sandoz 1g poeder voor oplossing voor injectie/infusie
	Ceftriaxone Sandoz 2 g poeder voor oplossing voor injectie/infusie
Tsjechië:	Ceftriaxon Sandoz 1 g
Estland:	Ceftriaxone Sandoz
Italië:	Ceftriaxone Sandoz GmbH 0,5 g polvere per soluzione iniettabile
	Ceftriaxone Sandoz GmbH 1 g polvere per soluzione iniettabile/per infusione
	Ceftriaxone Sandoz GmbH 2 g polvere per soluzione iniettabile/per infusione
Nederland:	Ceftriaxon Sandoz 0,5, poeder voor oplossing voor injectie 0,5 g
	Ceftriaxon Sandoz 1, poeder voor oplossing voor injectie/infusie 1 g
	Ceftriaxon Sandoz 2, poeder voor oplossing voor injectie/infusie 2 g
Portugal:	Ceftriaxona
Slowakije:	Ceftriaxon Sandoz 1 g prášok na injekčný a infúzny roztok
	Ceftriaxon Sandoz 2 g prášok na injekčný a infúzny roztok
Slovenië:	Ceftriakson Lek 1 g prašek za raztopino za injiciranje ali infundiranje
	Ceftriakson Lek 2 g prašek za raztopino za injiciranje ali infundiranje

Verenigd Koninkrijk: Ceftriaxone 1 g Powder for Solution for Injection/Infusion
Ceftriaxone 2 g Powder for Solution for Injection/Infusion

Deze bijsluiter is voor de laatste keer goedgekeurd in augustus 2021

The following information is intended for medical or healthcare professionals only:

Method and route of administration of [nationally approved name] powder and solvent for solution for injection/infusion

[Nationally approved name] may be administered by intravenous bolus injection, by intravenous infusion or by intramuscular injection after reconstitution of the solution according to the directions below.
Ceftriaxone should not be mixed in the same syringe with any drug other than 1 % lidocaine hydrochloride solution (for intramuscular injection only).

Do not use diluents containing calcium, such as Ringer's solution or Hartmann's solution, to reconstitute [Nationally approved name]. Particulate formation can result.

Intramuscular injection:
[Nationally approved name 0.25g] should be dissolved in 2 ml of 1 % lidocaine hydrochloride solution. [Nationally approved name 0.5g] should be dissolved in 2 ml of 1 % lidocaine hydrochloride solution. [Nationally approved name 1g] should be dissolved in 3.5 ml of 1 % lidocaine hydrochloride solution. The solution should be administered by deep intramuscular injection. Dosages greater than 1 g should be divided and injected at more than one site. Solutions of lidocaine should not be administered intravenously.

Intravenous injection: [Nationally approved name 0.5g] is dissolved in 5 ml and [Nationally approved name 1g] in 10 ml of water for injections. The injection should be administered over at least 2 – 4 minutes, directly into the vein or via the tubing of an intravenous infusion.

Intravenous infusion: [nationally approved name 1g] should be dissolved in 20 to 40 ml of one of the following calcium-free infusion solutions:
• sodium chloride 0.9%
• sodium chloride 0.45% and glucose 2.5%
• glucose 5 % or 10%
• dextran 6% in glucose 5%
• hydroxyethyl starch 6-10% infusions.

See also the section Miscibility below. The infusion should be administered over at least 30 minutes.

When reconstituted for intramuscular or intravenous injection, the white to yellowish-orange crystalline powder gives a pale yellow to amber solution.
Reconstituted solutions should be inspected visually. Only clear solutions free of visible particles should be used. The reconstituted product is for single use only and any unused solution must be discarded.

Miscibility
Solutions containing ceftriaxone should not be mixed with or added to other agents. In particular diluents containing calcium (e.g. Ringer's solution or Hartmann's solution), should not be used to reconstitute ceftriaxone vials or to further dilute a reconstituted vial for IV administration because a precipitate can form. **Ceftriaxone must not be mixed or administered simultaneously with calcium-containing solutions.**

Based on literature reports, ceftriaxone is not compatible with amsacrine, vancomycin, fluconazol, aminoglycosides and labetalol.