Package leaflet: Information for the user

Ceftriaxone 1 g powder for solution for injection/infusion
Ceftriaxone 2 g powder for solution for injection/infusion

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 Ceftriaxone is and what it is used for

Ceftriaxone 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.

Ceftriaxone 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.

This medicine 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 Ceftriaxone

You must not be given Ceftriaxone 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, monobactams or carbapenems). 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;
- you are allergic to lidocaine and you are to be given Ceftriaxone as an injection into a muscle.

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
Talk to your doctor, pharmacist or nurse before you are given Ceftriaxone if:
- you have recently received or are about to receive products that contain calcium;
- you have ever had problems with lidocaine;
- 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 Ceftriaxone for a long time, you may need to have regular blood tests. Ceftriaxone can affect the results of urine tests for sugar and a blood test known as the Coombs test.

If you need to take such tests, tell the person taking the sample that you have been given 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 measure your 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, pharmacist or nurse before your child is administered Ceftriaxone if your child has recently been given or is to be given a product that contains calcium into their vein.

Other medicines and Ceftriaxone
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 aminoglycosides;
- an antibiotic called chloramphenicol (used to treat infections, particularly of the eyes);
- medicines for preventing blood clots.

Pregnancy, 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 Ceftriaxone against the risk to your baby.

Driving and using machines

Ceftriaxone 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.

Ceftriaxone contains sodium
Ceftriaxone 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 4.15% of the recommended maximum daily dietary intake of sodium for an adult.

Ceftriaxone 2 g powder for solution for injection/infusion
This medicine contains 166 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 8.3% of the recommended maximum daily dietary intake of sodium for an adult.

3. How Ceftriaxone is given

Ceftriaxone is usually given by a doctor or nurse. 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.

Ceftriaxone 1 g powder for solution for injection/infusion can be given as a drip (intravenous infusion) or as an injection directly into a vein or into a muscle.

Ceftriaxone 2 g powder for solution for injection/infusion can be given as a drip (intravenous infusion) or injection into a muscle.

The usual dose
Your doctor will decide the correct dose of 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 Ceftriaxone 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 g 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 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.

Newborn babies (0-14 days)
- 20-50 mg 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 body weight.

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

If you are given more Ceftriaxone 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 Ceftriaxone
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 forgotten dose.

If you stop using Ceftriaxone
Do not stop taking Ceftriaxone 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 (frequency not known, 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;
- chest pain in the context of allergic reactions, which may be a symptom of allergy triggered cardiac infarction (Kounis syndrome).

Severe skin reactions (frequency not known, 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 Ceftriaxone treatment for infections with spirochete such as Lyme disease;
- Acute Generalised Exanthematous Pustulosis (AGEP) appears as a red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The most common location: mainly localized on the skin folds, trunk, and upper extremities.

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.
- Nausea or vomiting.
- Pruritus (itching).
- Pain or a burning feeling along the vein where Ceftriaxone 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.
- Treatment with ceftriaxone, particularly in elderly patients with serious kidney or nervous system problems may rarely cause decreased consciousness, abnormal movements, agitation and convulsions.
- 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.

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 abdomen 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).
- Inflammation and redness of the skin (erythema multiforme).
- 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).
- Ceftriaxone 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 HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Ceftriaxone

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 vial label and carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions.

Keep the vials in the outer carton in order to protect from light.

After reconstitution with lidocaine hydrochloride 10 mg/ml (1%) solution for intramuscular injection
Chemical and physical in-use stability has been demonstrated for 6 hours at 25°C.
From a microbiological point of view, unless the method of reconstitution precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

After reconstitution for intravenous injection
Chemical and physical in-use stability has been demonstrated for 48 hours at 2 to 8°C and 12 hours at 25°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 normally not be longer than 24 hours at 2 to 8°C, unless reconstitution has taken place in controlled and validated aseptic conditions.

After reconstitution for intravenous infusion
The reconstituted solution should be diluted immediately after reconstitution.

After dilution for intravenous infusion
Chemical and physical in-use stability has been demonstrated for 48 hours at 2 to 8°C and 12 hours at 25°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 normally not be longer than 24 hours at 2 to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

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 Ceftriaxone contains
– The active substance is ceftriaxone.

Ceftriaxone 1 g powder for solution for injection/infusion
Each vial contains 1 g of ceftriaxone (as ceftriaxone sodium).

Ceftriaxone 2 g powder for solution for injection/infusion
Each vial contains 2 g of ceftriaxone (as ceftriaxone sodium).

What Ceftriaxone looks like and contents of the pack
Almost white or yellowish powder.

Ceftriaxone 1 g powder for solution for injection/infusion
Powder is filled in colourless glass vial closed with grey bromobutyl rubber stopper covered with aluminium cap and dark blue plastic flip-off cap.

Ceftriaxone 2 g powder for solution for injection/infusion
Powder is filled in colourless glass vial closed with grey bromobutyl rubber stopper covered with aluminium cap and orange plastic flip-off cap.

The vials are placed in outer cartons.

Pack sizes: 1 or 10 vials.

Not all pack sizes may be marketed.

Marketing authorisation holder and Manufacturer
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This medicine is authorised in the Member States of the European Economic Area under the following names:

Finland	Ceftriaxone Kalceks 1 g, 2 g injektio-/infuusiokuiva-aine liuosta varten
Austria, Germany	Ceftriaxon Kalceks 1 g Pulver zur Herstellung einer Injektions-/Infusionslösung Ceftriaxon Kalceks 2 g Pulver zur Herstellung einer Injektions-/Infusionslösung
Czech Republic, Italy, Poland	Ceftriaxone Kalceks
Belgium	Ceftriaxone Kalceks 1 g, 2 g poeder voor oplossing voor injectie/infusie Ceftriaxone Kalceks 1 g, 2 g poudre pour solution injectable/pour perfusion Ceftriaxone Kalceks 1 g, 2 g Pulver zur Herstellung einer Injektions-/Infusionslösung
Croatia	Ceftriakson Kalceks 1 g, 2 g prašak za otopinu za injekciju/infuziju
Denmark, Norway	Ceftriaxon Kalceks
France	CEFTRIAXONE KALCEKS 1 g poudre pour solution injectable/pour perfusion CEFTRIAXONE KALCEKS 2 g poudre pour solution injectable/pour perfusion
Hungary	Ceftriaxone Kalceks 1 g és 2 g por oldatos injekcióhoz vagy infúzióhoz
Ireland	Ceftriaxone 1 g, 2 g powder for solution for injection/infusion
Latvia	Ceftriaxone Kalceks 1 g, 2 g pulveris injekciju/infūziju šķīduma pagatavošanai
Lithuania	Ceftriaxone Kalceks 1 g, 2 g milteliai injekciniam ar infuziniam tirpalui
The Netherlands	Ceftriaxon Kalceks 1 g, 2 g poeder voor oplossing voor injectie/infusie
Slovakia	Ceftriaxone Kalceks 1 g, 2 g prášok na injekčný/infúzny roztok
Slovenia	Ceftriakson Kalceks 1 g, 2 g prašek za raztopino za injiciranje/infundiranje
Spain	Ceftriaxona Kalceks 1 g, 2 g polvo para solución inyectable y para perfusión

This leaflet was last revised in 05/2024

The following information is intended for healthcare professionals only:

Please refer to the Summary of Product Characteristics for full prescribing information.

Method of administration
Ceftriaxone 1 g powder for solution for injection/infusion can be used for IM injection, slow IV injection and IV infusion.
Ceftriaxone 2 g powder for solution for injection/infusion can be used for IM injection and IV infusion.

Incompatibilities
Based on literature reports, ceftriaxone is not compatible with amsacrine, vancomycin, fluconazole, and aminoglycosides.

This medicinal product must not be mixed with other medicinal products except those mentioned below.

In particular diluents containing calcium (e.g. Ringer's solution, Hartmann's solution) should not be used to reconstitute ceftriaxone powder in vials or to further dilute a reconstituted content for intravenous administration because a precipitate can form. Ceftriaxone must not be mixed or administered simultaneously with calcium-containing solutions including total parenteral nutrition.

If the treatment consists of a combination of another antibiotic and ceftriaxone, do not administer in the same syringe or infusion solution.

For single use only.

See section 5 for storage conditions of the reconstituted and diluted solutions.

Compatibility with the following solutions has been demonstrated:
- water for injections;
- lidocaine hydrochloride 10 mg/ml (1%) solution (for intramuscular use only);
- sodium chloride 9 mg/ml (0.9%) solution;
- glucose 50 mg/ml (5%) solution;
- glucose 100 mg/ml (10%) solution;
- sodium chloride 4.5 mg/ml (0.45%) and glucose 25 mg/ml (2.5%) solution.

Intramuscular injection
For intramuscular injection, 1 g of ceftriaxone is dissolved in 3.5 ml of 1% lidocaine hydrochloride solution, or 2 g of ceftriaxone is dissolved in 7 ml of 1% lidocaine hydrochloride solution.
The solution should be given by deep intramuscular injection. Doses greater than 1 g should be divided and injected into more than one site. For doses greater than 2 g intravenous administration should be used. Intramuscular administration should be considered when the intravenous route is not possible or less appropriate for the patient.
Ceftriaxone should not be mixed with other medicines in the same syringe, except for 1% lidocaine hydrochloride solution (for intramuscular injection only).
As the solvent used is lidocaine, the resulting solution should never be administered intravenously.

Intravenous injection
For intravenous injection, 1 g of ceftriaxone is dissolved in 10 ml of water for injections. The injection is given directly into a vein or via intravenous infusion line over 5 minutes.
Concentration of ceftriaxone in the final solution for intravenous injection is 93 mg/ml.

Intravenous infusion
For intravenous infusion, 1 g or 2 g of ceftriaxone are dissolved and, if necessary, further diluted with one of the compatible calcium-free solutions listed above (except lidocaine hydrochloride solution since lidocaine solutions should never be administered intravenously).
Concentration of ceftriaxone in the final solution for intravenous infusion is 48 mg/ml:

Ceftriaxone powder	Volume of diluent	Concentration of ceftriaxone in the final solution
1 g	20 ml	48 mg/ml
2 g	40 ml*	48 mg/ml

* First, the powder is reconstituted in 20 ml of compatible diluent. The reconstituted solution is further diluted with 20 ml of compatible diluent to concentration 48 mg/ml using appropriate administration device (e.g. infusion pump, infusion bag).

It is recommended that the intravenous infusion line is flushed after each administration with sodium chloride 9 mg/ml (0.9%) solution for injection to ensure administration of the complete dose.

The infusion should be administered over at least 30 minutes.

In neonates, intravenous doses should be given over 60 minutes to minimize the risk of bilirubin encephalopathy.

The colour of the solution after reconstitution/dilution is slightly yellowish to brownish yellow, depending on the duration of storage, concentration and solvent used, but this does not affect the efficacy of the medicinal product.

Reconstituted/diluted solutions should be visually inspected prior to use. Only clear solutions free from visible particles should be used. The reconstituted product is for single use only and any unused solution must be discarded.

This medicinal product may pose a risk to the environment.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.