UBTR-1390-800

Package leaflet: Information for the patient

hameln

Ceftriaxone 1 g powder for solution for injection/infusion
Ceftriaxone 2 g powder for solution for injection/infusion
ceftriaxone (as ceftriaxone sodium)

Read 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.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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

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 Ceftriaxone

You must not be given Ceftriaxone if:
- you are allergic to ceftriaxone
- 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 breathe 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 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 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 are having 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 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, pharmacist or nurse before your child is administered Ceftriaxone:
- if he/she 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 an aminoglycoside
- an antibiotic called chloramphenicol (used to treat infections, particularly of the eyes)

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

This medicine contains 83 mg sodium (main component of cooking/table salt) in each 1 g vial. This is equivalent to 4.15% of the recommended maximum daily dietary intake of sodium for an adult.

This medicine contains 166 mg sodium (main component of cooking/table salt) in each 2 g vial. This is equivalent to 8.30% of the recommended maximum daily dietary intake of sodium for an adult.

Preparing the medicine for administration – see the section ”The following information is intended for health care professionals only” at the end of this package leaflet. The amount of sodium obtained from the diluent should be taken into account when calculating the total sodium content in the final product solution.

For detailed information on the sodium content of the solution used for dilution, please refer to the patient information leaflet for the diluent used.

3. How Ceftriaxone is given

Ceftriaxone 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 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 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 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 of 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 of 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.

The following information is intended for healthcare professionals only:

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

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

Calcium-containing diluents, such as Ringer’s solution or Hartmann’s solution, should not be used to reconstitute Ceftriaxone vials or to further dilute a reconstituted vial for intravenous administration because a precipitate can form. Precipitation of ceftriaxone-calcium salt can also occur when ceftriaxone is mixed with calcium-containing solutions in the same intravenous administration line. Therefore, ceftriaxone and calcium-containing solutions must not be mixed or administered simultaneously.

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

Posology

The dose depends on the severity, susceptibility, site and type of infection and on the age and hepato-renal function of the patient.

The doses recommended in the tables below are the generally recommended doses in these indications. In particularly severe cases, doses at the higher end of the recommended range should be considered.

Adults and children over 12 years of age (≥50 kg)

Ceftriaxone dosage*	Treatment frequency**	Indications
1-2 g	Once daily	Community acquired pneumonia
		Acute exacerbations of chronic obstructive pulmonary disease
		Intra-abdominal infections
		Complicated urinary tract infections (including pyelonephritis)
2 g	Once daily	Hospital acquired pneumonia
		Complicated skin and soft tissue infections
		Infections of bones and joints
2-4 g	Once daily	Management of neutropenic patients with fever that is suspected to be due to a bacterial infection
		Bacterial endocarditis
		Bacterial meningitis

* In documented bacteraemia, the higher end of the recommended dose range should be considered.
** Twice daily (12 hourly) administration may be considered where doses greater than 2 g daily are administered.

Indications for adults and children over 12 years of age (≥50 kg) that require specific dosage schedules:

Acute otitis media
A single intramuscular dose of Ceftriaxone 1-2 g can be given.
Limited data suggest that in cases where the patient is severely ill or previous therapy has failed, Ceftriaxone may be effective when given as an intramuscular dose of 1-2 g daily for 3 days.

Pre-operative prophylaxis of surgical site infections
2 g as a single pre-operative dose.

Gonorrhoea
500 mg as a single intramuscular dose.

Syphilis
The generally recommended doses are 500 mg-1 g once daily increased to 2 g once daily for neurosyphilis for 10-14 days. The dose recommendations in syphilis, including neurosyphilis, are based on limited data. National or local guidance should be taken into consideration.

Disseminated Lyme borreliosis (early [Stage II] and late [Stage III])
2 g once daily for 14-21 days. The recommended treatment durations vary and national or local guidelines should be taken into consideration.

Paediatric population
Infants and children 15 days to 12 years of age (<50 kg)
For children with bodyweight of 50 kg or more, the usual adult dosage should be given.

Ceftriaxone dosage*	Treatment frequency**	Indications
50-80 mg/kg	Once daily	Intra-abdominal infections
		Complicated urinary tract infections (including pyelonephritis)
		Community acquired pneumonia
		Hospital acquired pneumonia
50-100 mg/kg (max 4 g)	Once daily	Complicated skin and soft tissue infections
		Infections of bones and joints
		Management of neutropenic patients with fever that is suspected to be due to a bacterial infection
80-100 mg/kg (max 4 g)	Once daily	Bacterial meningitis
100 mg/kg (max 4 g)	Once daily	Bacterial endocarditis

* In documented bacteraemia, the higher end of the recommended dose range should be considered.
** Twice daily (12 hourly) administration may be considered where doses greater than 2 g daily are administered.

Indications for neonates, infants and children 15 days to 12 years (<50 kg) that require specific dosage schedules:

Acute otitis media
For initial treatment of acute otitis media, a single intramuscular dose of Ceftriaxone 50 mg/kg can be given. Limited data suggest that in cases where the child is severely ill or initial therapy has failed, Ceftriaxone may be effective when given as an intramuscular dose of 50 mg/kg daily for 3 days.

Pre-operative prophylaxis of surgical site infections
50-80 mg/kg as a single pre-operative dose.

Syphilis
The generally recommended doses are 75-100 mg/kg (max 4 g) once daily for 10-14 days. The dose recommendations in syphilis, including neurosyphilis, are based on very limited data. National or local guidance should be taken into consideration.

Disseminated Lyme borreliosis (early [Stage II] and late [Stage III])
50-80 mg/kg once daily for 14-21 days. The recommended treatment durations vary and national or local guidelines should be taken into consideration.

Neonates 0-14 days
Ceftriaxone is contraindicated in premature neonates up to a postmenstrual age of 41 weeks (gestational age + chronological age).

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 missed 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:

Treatment with ceftriaxone, particularly in elderly patients with serious kidney or nervous system problems may rarely cause decreased consciousness, abnormal movements, agitation and convulsions.

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
- chest pain in the context of allergic reactions, which may be a symptom of allergy triggered cardiac infarction (Kounis syndrome)

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 ceftriaxone 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 or genital fungal infections)
- a decrease in the number of white blood cells (granulocytopenia)
- reduction in the 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 Ceftriaxone 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)

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)
- 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

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)
- 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 to Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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.

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

Good practice principles indicate that solutions should be prepared immediately before use.
Shelf life after reconstitution/dilution:

Ceftriaxone after reconstitution/dilution for intramuscular injection, intravenous injection and infusions is chemically and physically stable in all recommended solvents:
- for 24 hours at a temperature below 25°C,
- for 24 hours at 2°C to 8°C (in refrigerator).

The reconstituted product does not require protection from light.
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 not be longer than the times stated above for the chemical and physical in-use stability.

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

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. Each vial contains 1 g or 2 g of ceftriaxone as ceftriaxone sodium.
- There are no other ingredients.

What Ceftriaxone looks like and contents of the pack

The medicine is almost white or yellowish powder.

Ceftriaxone is supplied in 20 ml glass vial made of colourless glass of third hydrolytic class closed with a bromobutyl rubber stopper, aluminium cap or aluminium cap and plastic flip-off. 10 vials with label and information leaflet are packed in cardboard box.

Pack sizes: 10 vials

Marketing Authorisation Holder

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Nexus, Gloucester Business Park
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United Kingdom

Manufacturer

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Ceftriaxone dosage*	Treatment frequency	Indications
20-50 mg/kg	Once daily	Intra-abdominal infections
		Complicated skin and soft tissue infections
		Complicated urinary tract infections (including pyelonephritis)
		Community acquired pneumonia
		Hospital acquired pneumonia
		Infections of bones and joints
		Management of neutropenic patients with fever that is suspected to be due to a bacterial infection
50 mg/kg	Once daily	Bacterial meningitis
		Bacterial endocarditis

* In documented bacteraemia, the higher end of the recommended dose range should be considered.
A maximum daily dose of 50 mg/kg should not be exceeded.

Indications for neonates 0-14 days that require specific dosage schedules:

Acute otitis media
For initial treatment of acute otitis media, a single intramuscular dose of Ceftriaxone 50 mg/kg can be given.

Pre-operative prophylaxis of surgical site infections
20-50 mg/kg as a single pre-operative dose.

Syphilis
The generally recommended dose is 50 mg/kg once daily for 10-14 days. The dose recommendations in syphilis, including neurosyphilis, are based on very limited data. National or local guidance should be taken into consideration.

Duration of therapy
The duration of therapy varies according to the course of the disease. As with antibiotic therapy in general, administration of ceftriaxone should be continued for 48-72 hours after the patient has become afebrile or evidence of bacterial eradication has been achieved.

Older people
The dosages recommended for adults require no modification in older people provided that renal and hepatic function is satisfactory.

Patients with hepatic impairment
Available data do not indicate the need for dose adjustment in mild or moderate liver function impairment provided renal function is not impaired.

There are no study data in patients with severe hepatic impairment (see section 5.2).

Patients with renal impairment
In patients with impaired renal function, there is no need to reduce the dosage of ceftriaxone provided hepatic function is not impaired. Only in cases of preterminal renal failure (creatinine clearance <10 ml/min) should the ceftriaxone dosage not exceed 2 g daily.
In patients undergoing dialysis no additional supplementary dosing is required following the dialysis. Ceftriaxone is not removed by peritoneal- or haemodialysis. Close clinical monitoring for safety and efficacy is advised.

Patients with severe hepatic and renal impairment
In patients with both severe renal and hepatic dysfunction, close clinical monitoring for safety and efficacy is advised.

Method of administration

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

The use of freshly prepared solutions is recommended. For storage conditions of the reconstituted medicinal product, see section "How to store Ceftriaxone".

After the solvent is added to the vial contents, the vial should be shaken until the powder dissolves; the solution should be clear after 1-2 minutes.

Prior to administration, the solution should be inspected for clearness and insoluble matter.

Intramuscular injection

The product should be diluted with an appropriate volume of 1% lidocaine hydrochloride solution.

Dose	Volume of solvent	Solution concentration	Displacement volume
1 g	3.5 ml	238 mg/ml	0.7 ml
2 g	7 ml	238 mg/ml	1.4 ml

The drug should be administered by deep intramuscular injection.
The drug should not be mixed in the same syringe with any drug other than 1% lidocaine hydrochloride solution.
Doses greater than 1 g should be divided and injected at more than one site.
For doses greater than 2 g, intravenous administration should be used.
Solutions in Lidocaine should never be administered intravenously.

The displacement volume of 1 g of Ceftriaxone is 0.7 ml in 1% lidocaine hydrochloride solution. This requires the offset of solvent volume to facilitate weight-dependent dosing (primarily in children up to 12 years), if only part of the total solution is measured and administered. To prepare a final solution concentration of 285 mg/ml, reconstitute 1 g of Ceftriaxone in 2.8 ml of in 1% lidocaine hydrochloride solution.

The displacement volume of 2 g of Ceftriaxone is 1.4 ml in 1% lidocaine hydrochloride solution. This requires the offset of solvent volume to facilitate weight-dependent dosing (primarily in children up to 12 years), if only part of the total solution is measured and administered. To prepare a final solution concentration of 100 mg/ml, reconstitute 2 g of Ceftriaxone in 5.6 ml of in 1% lidocaine hydrochloride solution.

Intravenous injection (should be administered slowly over 5 minutes)

1 g of Ceftriaxone should be dissolved in 10 ml water for injection.

2 g of Ceftriaxone should be dissolved in 20 ml water for injection.

Dose	Volume of solvent	Solution concentration	Displacement volume
1 g	10 ml	93.5 mg/ml	0.7 ml
2 g	20 ml	93.5 mg/ml	1.4 ml

Solutions in Lidocaine should never be administered intravenously.

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

The displacement volume of 1 g of Ceftriaxone is 0.7 ml in water for injections. This requires the offset of solvent volume to facilitate weight-dependent dosing (primarily in children up to 12 years), if only part of the total solution is measured and administered. To prepare a final solution concentration of 100 mg/ml, reconstitute 1 g of Ceftriaxone in 9.3 ml of water for injections.

The displacement volume of 2 g of Ceftriaxone is 1.4 ml in water for injections. This requires the offset of solvent volume to facilitate weight-dependent dosing (primarily in children up to 12 years), if only part of the total solution is measured and administered. To prepare a final solution concentration of 100 mg/ml, reconstitute 2 g of Ceftriaxone in 18.6 ml of water for injections

Intravenous infusion (should be administered over at least 30 minutes)

In order to prepare an intravenous infusion solution of 50 mg/ml Ceftriaxone, 1 g should be dissolved in 20 ml, and 2g should be dissolved in 40 ml of one of the following calcium-free solutions:
- 0.9% NaCl solution,
- 5% glucose solution,
- 5% glucose solution with 0.9% sodium chloride solution (prepared in a 1:1 ratio),
- 5% glucose solution with 0.9% sodium chloride solution (prepared in a 2:1 ratio),
- Water for injections.

The solution thus obtained should be further diluted with the same solution as used for dissolution.

Dose	Total volume of solvent	Approximate solution concentration	Displacement volume
1 g	20 ml	50 mg/ml	0.7 ml
2 g	40 ml	50 mg/ml	1.4 ml

Solutions in Lidocaine should never be administered intravenously.

The solution of Ceftriaxone may be colourless to yellow; the colour intensity depends on the concentration of ceftriaxone and diluent used.

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