

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Ceftriaxone 2 g powder for solution for injection or infusion

Ceftriaxone (as Ceftriaxone Sodium)

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
- 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

This medicine will be referred to as Ceftriaxone Injection in this leaflet.

What is in this leaflet

1. What Ceftriaxone Injection is and what it is used for
2. What you need to know before you are given Ceftriaxone Injection
3. How Ceftriaxone Injection is given
4. Possible side effects
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1. What Ceftriaxone Injection is and what it is used for

Ceftriaxone Injection 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 Injection 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 Injection

You must not be given Ceftriaxone Injection 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 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 Injection 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 whites of the eyes) or is about 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 Ceftriaxone Injection 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
- 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

If you need a blood or urine test

If you are given Ceftriaxone Injection for a long time, you may need to have regular blood tests. Ceftriaxone Injection 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 Injection

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 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 Injection

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 Ceftriaxone Injection against the risk to your baby.

Driving and using machines

Ceftriaxone Injection 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 Injection contains sodium

Each gram of ceftriaxone injection contains approximately 3.6 mmol of sodium, equivalent to 4% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

3. How Ceftriaxone Injection is given

Ceftriaxone Injection 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 Injection 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 Injection 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 Injection 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



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The following information is intended for healthcare professionals only:

Instructions for reconstitution

The medicinal product as such is not intended for immediate use and it has to be reconstituted with diluent before administration.

Concentration for the intravenous injection: 100 mg/mL, Concentration for the intravenous infusion: 50 mg/mL

Reconstitution: From the calculated dose, determine the appropriate number of vials to be used. For the intravenous or intramuscular injection, add the recommended volume of reconstitution solution specified in the table below and shake well until the contents of the vial have dissolved completely.

For the intravenous infusion, add 20 mL of reconstitution solution and shake well until the contents of the vial have dissolved completely.

Draw up this 20 mL of reconstituted solution and add it to 20 mL of reconstitution fluid in an infusion bag (making a total volume of 40 mL reconstitution fluid as specified in the table).

The solution should be given by intravenous infusion as detailed in section 4.2. of the Summary of Product Characteristics

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 Injection 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 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 Injection you will need and will check you closely depending on the severity of the liver and kidney disease.

If you are given more Ceftriaxone Injection 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 Injection

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 Injection

Do not stop taking Ceftriaxone Injection 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
- Chest pain in the context of allergic reactions, which may be a symptom of allergy triggered cardiac infarction (Kounis syndrome)

Severe skin rashes (not known, frequency cannot be estimated from the available data)

If you get a severe skin rash, 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

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
- Pruritus (itching)
- Pain or a burning feeling along the vein where Ceftriaxone Injection 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

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 Injection 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 Yellow Card Scheme Website:

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 Injection

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

Do not use Ceftriaxone Injection 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.

Store the unopened vial below 25 °C. Keep container in the outer carton.

Once the powder has been dissolved; the solution should be used immediately or stored at 2-8 °C for 24 hours, or stored at 25 °C ± 2 °C for 6 hours.

If the solution is cloudy, it should not be used. Any unused solution should be discarded.

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required.

These measures will help protect the environment.

6. Contents of the pack and other information

What Ceftriaxone Injection contains

The active substance in Ceftriaxone Injection is Ceftriaxone Sodium.

What Ceftriaxone looks like and contents of the pack

Ceftriaxone is a white to slightly yellow powder. It is supplied in 2 g vials with 1, 5, 10, 25 or 50 vials in a carton.

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PLGB 57592/0005 Ceftriaxone Sodium 2g Powder for Solution for Injection or Infusion

Marketing Authorisation Holder:

AFT Pharma UK Limited
Olympia House,
Unit 13, 2nd Floor, Armitage Road,
London, NW11 8RQ
England

Manufacturer:

Elara Pharmservices Limited
5 Garden Court,
Lockington Hall,
Main Street, Lockington,
Derby, DE74 2RH,
United Kingdom

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	Powder	Solution for reconstitution	Quantity of Solution	Displacement Volume
Intramuscular Injection	2 g	1% Lignocaine Hydrochloride Injection*	7 mL	0.63 mL
Intravenous Injection	2 g	Sterile Water for Injection	20 mL	0.63 mL
Intravenous Infusion	2 g	5% Dextrose Injection 10% Dextrose Injection 0.9% Sodium Chloride Injection Sodium Chloride and Dextrose Injection (0.45% sodium chloride + 2.5% dextrose) Dextran 6% in Dextrose Injection 5% Sterile Water for Injection Hydroxyethyl starch 6% infusions**	40 mL	1.25 mL

*Solutions of Ceftriaxone in lignocaine should not be administered intravenously

**Formulae;

6% infusion: 30 g hydroxyethyl starch, 4.5 g sodium chloride, up to 500 mL Water for Injection.

If other infusion fluids are used, compatibility with Ceftriaxone should be checked. The solution should be clear, do not use the solution if particles are present.