PACKAGE LEAFLET

Package leaflet: Information for the patient

Ceftriaxone 1g powder for solution for injection/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.

The name of your medicine is **Ceftriaxone 1g powder for solution for injection/infusion**. In the rest of this leaflet the name of the medicine shall be Ceftriaxone.

What is in this leaflet

1. What Ceftriaxone is and what it is used for
2. What you need to know before you are given Ceftriaxone
3. How Ceftriaxone is given
4. Possible side effects
5. How to store Ceftriaxone
6. Contents of the pack and other information

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 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, 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 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 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 or pharmacist 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.

Sodium
This medicine contains 82,86 mg sodium (main component of cooking/table salt) in each 1g vial. This is equivalent to 4,1% 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. 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 recommended 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 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 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 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 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, a burning feeling, pain, 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).
- 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.
- 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 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

Store below 25°C. Keep the vials in the outer carton in order to protect from light.
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 and carton after EXP. The expiry date refers to the last day of that month.

From a microbiological point of view, the product should be used immediately. If not used immediately, inuse 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 throw away any medicines via wastewater. Ask your pharmacist 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 (as ceftriaxone sodium). Ceftriaxone is supplied in glass vials containing 1g of ceftriaxone.
- There are no other ingredients in Ceftriaxone.

What Ceftriaxone looks like and contents of the pack
Ceftriaxone 1g powder for solution for injection/infusion is an almost white or yellowish crystalline powder for solution for injection/infusion. The product is available in glass vials in packs of 1, 10, and 50 vials.
Before it is given to the patient, Ceftriaxone is made into a solution by adding sterile liquid to the vial. The correct dose is then taken out of the vial. It can be given to the patient either as an injection or added to a bag of infusion solution which is given through a small tube into one of your veins.

Not all pack sizes may be marketed.

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This medicine is authorised in the Member States of the European Economic Area under the following names:

Portugal:	Ceftriaxona BRADEX
Austria:	Ceftriaxon BRADEX 1g Pulver zur Herstellung einer Injektions-/Infusionslösung
Czech Republic:	Ceftriaxone Noridem
Germany:	Ceftriaxon Noridem 1g Pulver zur Herstellung einer Injektions-/Infusionslösung
Spain:	Ceftriaxona Noridem 1 g polvo para solución inyectable y para perfusión EFG
France:	CEFTRIAXONE NORIDEM 1g, poudre pour solution injectable/pour perfusion
Hungary:	Ceftriaxon Noridem 1 g por oldatos injekcióhoz vagy infúzióhoz
Ireland:	Ceftriaxone 1g powder for solution for injection/infusion
Italy:	Ceftriaxone Noridem
Poland:	Ceftriaxone Noridem
Slovak Republic:	Ceftriaxone Noridem

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