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, which may cause pain, feeling sick and being sick.
- 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 Yellow Card Scheme at 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

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

Store below 30°C. Keep the vials in the original packaging in order to protect from light.
After reconstitution:
Chemical and physical in-use stability has been demonstrated for 6 hours at 25°C and for 24 hours at 2-8°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.

If the solvent for reconstitution is Hydroxyethyl Starch 6%, potency is only maintained for maximum 6 hours at 2-8°C.

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

What Ceftriaxone looks like and contents of the pack
This medicine is supplied in a glass vial as powder for solution for injection/infusion.
Box of 1, 5 or 10 vial(s). Not all pack size may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing authorisation holder
PANPHARMA
ZI du Clairay
35133 Luitré
France

Manufacturer
PANPHARMA
ZI du Clairay
35133 Luitre
France

This medicinal product is authorised in the Member States of the EEA under the following names:

France:	Ceftriaxone PANPHARMA 1 g, poudre pour solution injectable
United Kingdom:	Ceftriaxone 1 g Powder for Solution for Injection
Germany:	Ceftriaxon PANPHARMA 1 g Pulver zur Herstellung einer Injektionslösung

This leaflet was last revised in December 2019.

Instruction for Healthcare professionals

Preparation of solutions for injection and infusion

The use of freshly prepared solutions is recommended.

The reconstitution solvents are Lidocaine Hydrochloride solution, Water for Injections, Sodium Chloride 0,9%, Glucose 5% or Hydroxyethyl Starch 6% infusion.
These maintain potency for maximum 6 hours at or below 25°C or 24 hours at 2-8°C. Protect from light.

If the solvent for reconstitution is Hydroxyethyl Starch 6%, potency is only maintained for maximum 6 hours at 2-8°C.

Ceftriaxone, powder for solution for injection, should not be mixed in the same syringe with any drug other than 1.06% Lidocaine Hydrochloride solution (for intramuscular injection only).

Intramuscular injection: Ceftriaxone 1g powder for solution for injection/infusion should be dissolved in 3.5 ml of 1.06% Lidocaine Hydrochloride solution.

Package Leaflet: information for the user

Ceftriaxone 1 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.

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);
- 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;
- 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;
- if 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 Ceftriaxone:
- if 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 have recently received or are about to receive products that contain calcium;
- if 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);
- if you have liver or kidney problems;
- if you have gall stones or kidney stones;

- if 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).

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.

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
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
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 vial. This is equivalent to 4% 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 treatment with 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 (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 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 (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.

Severe hepatobiliary disorders (not known, frequency cannot be estimated from the available data)
If you get an inflammation of the liver, tell the doctor straight away.
- The signs might include unwell feeling, yellowing of the whites of the eyes, dark urine, itching of the skin, a tendency to bleed or disturbances of thought or wakefulness (these can be signs and symptoms of inflammation of the liver potentially leading to life-threating liver failure).

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 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.

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 in Lidocaine should not be administered intravenously.

Intravenous injection: Ceftriaxone 1g powder for solution for injection/infusion in 10 ml of Water for Injections. The injection should be administered over 5 minutes, directly into the vein or via the tubing of an intravenous infusion.

Intravenous infusion: Ceftriaxone 1 g powder for solution for injection/ infusion should be dissolved in 20 ml of one of the following calcium-free solutions: Sodium Chloride 0,9%, Glucose 5%, or Hydroxyethyl Starch 6% infusion. The infusion should be administered over at least 30 minutes.

Concentrations for the intramuscular injection: 285,7 mg/ml
Concentrations for the intravenous injection: 100 mg/ml
Concentrations for the intravenous infusion: 50 mg/ml