

Package leaflet: Information for the user

Gebecef 1g (Ceftriaxone for Injection USP 1g)

Read all of this leaflet carefully before you are given/taking 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 or pharmacist or nurse.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed 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
5. How to store Ceftriaxone Injection
6. Contents of the pack and other information

The name of your medicine is Gebecef 1g (Ceftriaxone for Injection USP 1g) but will be referred to as Ceftriaxone or as Ceftriaxone Injection throughout this leaflet.

1. What Ceftriaxone Injection is and what it is used for

What Ceftriaxone Injection is

Ceftriaxone Injection is an antibiotic given to adults and children. It works by killing bacteria that cause infections. It belongs to a group of medicine called cephalosporins.

What Ceftriaxone Injection is used for

Ceftriaxone Injection is used to treat infections caused by bacteria:

- It can be used to treat infections in different parts of the body including the lungs (pneumonia), blood (septicaemia), skin, other soft body parts (tissues), bone, and for infections such as meningitis and gonorrhoea (a sexually transmitted infection).
- It can be used to treat infections in people with low numbers of white blood cells (neutropenia).
- It can also be given before and after operations to stop infections from happening.

It works by stopping the bacteria from growing properly. This causes the bacteria to die.

2. What you need to know before you are given Ceftriaxone Injection

Do not take Ceftriaxone Injection if:

- You are allergic (hypersensitive) to ceftriaxone
- You are allergic to antibiotics called ‘cephalosporins’. These include cefalexin, cefaclor and cefuroxime.
- You have had a sudden or severe allergic reaction to penicillin or similar antibiotics (such as amoxicillin or flucloxacillin). 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, 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. You must not be given ceftriaxone if any of the above apply to you. If you are not sure, talk to your doctor or nurse before having ceftriaxone.

Warnings and precautions

Talk to your doctor or pharmacist or nurse before taking ceftriaxone injection

Take special care with ceftriaxone if:

- You have had a mild allergic reaction to penicillin or similar antibiotics (such as a skin rash which may have been itchy).
- You are allergic to anything not already mentioned in this leaflet.
- You have asthma.
- You have recently received or are about to receive calcium.
- You have ever had problems with your gut, in particular colitis (inflammation which causes abdominal pain or diarrhoea).
- You have liver or kidney problems.
- You have other illnesses, such as blood problems.
- You are on a low sodium diet.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Ceftriaxone Injection

Children and adolescents

Ceftriaxone Injection must not be given to babies if:

- The baby is premature.
- The baby is newborn (up to 28 days) and has certain blood problems or jaundice (yellowing of the skin or the whites of the eyes caused by liver or blood problems) or is about to be given another injection that contains calcium.

Other medicines and Ceftriaxone Injection

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.

This includes medicines you buy without a prescription, including herbal medicines. This is because ceftriaxone Injection affect the way some other medicines work. Also some medicines can affect the way ceftriaxone Injection work.

Tell your doctor if you are taking any one of the following:

- 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 or pharmacist 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 can cause dizziness. Talk to your doctor if any of these happens to you and do not drive or use any tools or machines.

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 recommended dose is:

Adults, older people and children aged 12 years and over with a body weight greater than Or equal to 50 kilograms (kg):

- The usual dose is 1 g (gram) once a day. If you have a severe infection, your doctor may give you a higher dose (between 2 g and 4 g once a day).
- If you are going to have an operation you may be given between 1 g and 2 g in one or two injections.

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:

- The dose is worked out by the doctor based on the baby's weight. The medicine is usually given to the baby once a day through a small tube into a vein (intravenous infusion). This usually takes at least 1 hour.

People with Liver and kidney problems:

- If you have problems with your liver and kidneys, you may be given a lower dose. You may need to have blood tests to check that you are getting the dose you need.

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.

4. Possible Side Effect

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 (uncommon, affect less than 1 in 100 people)

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 (very rare, affect less than 1 in 10,000 people). 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 (affect less than 1 in 10 people):

- Loose stools or diarrhoea.
- Feeling sick or being sick.

Uncommon (affect less than 1 in 100 people):

Fungal infections

A decrease in the number of white blood cells

Reduction in number of red blood cells

Headache

Dizziness.

Feeling sick or being sick.

Pruritis

Rare (affect less than 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, 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 Injection may interfere with some types of blood glucose tests - please check with your doctor

5. How to store Ceftriaxone Injection

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 last day of the month.

This medicinal product does not require any special storage conditions.

Store in dry place at temperature below 30°C.

Keep out of the sight and reach of children.

For single use only. Discard any unused solution.

Prepared solution should be used immediately.

Do not use this medicine if you notice any particulate matter and discoloration prior to administration. The solution should only be used if the solution is clear and free from particles.

Do not throw away any medicines via wastewater. 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 Injection contains:**

The active ingredient in this medicinal product is ceftriaxone sodium.

Each vial contains:

Sterile Ceftriaxone Sodium

Eq. to Ceftriaxone.....1g

What Ceftriaxone looks like and contents of the pack

Ceftriaxone for injection is white or yellowish orange crystalline powder. It is supplied in 10 ml glass vial along with sterile water for injection in a pack.

Marketing Authorization Holder and Manufacturer

Marketing Authorization Holder:

GB Pharma Limited
65, Chatsworth Road, London NW2 4BG,

Manufacturer:

Nectar Lifesciences Limited, Unit -VI
Vill. Bhatolikalan (Adjoining Jharmajri EPIP),
P.O. Barotiwala, Teh. Baddi,
Distt. Solan (H.P.) 174103, INDIA

Date of PIL revision: Not Applicable.