Package leaflet: Information for the user
Ceftriaxone 1g Powder for solution for injection or infusion
Read all of this leaflet before you start taking this medicine, because it contains important information for you.

Keep this leaflet. You may need to read it again.

If you have further questions, ask your doctor, pharmacist or nurse.

This medicine has been prescribed for you. 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.

Section 4
The name of your medicine is ceftriaxone 1g powder for solution for injection or infusion and ceftriaxone 2g powder for solution for injection or infusion. In the rest of this leaflet it is called ceftriaxone.

What is in this leaflet?
1. What ceftriaxone is and is it 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 (encephalitis)
- the lungs (pneumonia)
- the abdomen and abdominal wall (peritonitis)
- the urinary tract and kidneys
- bones and joints
- the skin (soft tissue infections)
- the blood
- the heart.

It can be given:
- to treat specific sexually transmitted infections (gonorrhoea and syphilis)
- to treat patients with HIV or AIDS who have an increased risk of infections (neutropenia) who have fewer than 300 white blood cells per microlitre (neutrophils) who have recently had bacterial infection.
- to treat infections of the chest in adults with chronic bronchitis or chronic obstructive pulmonary disease (COPD).
- to treat Lyme disease (caused by the bacterium Borrelia burgdorferi) in adults and children including newborn babies from 15 days of age and younger.
- to prevent infections during surgery.

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 infections
- you have ever had problems with your gut, in particular colitis (inflammation of the bowel)
- you have ever had an 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 if you are allergic to the drug.
- you have had any other allergic reactions to this medicine.

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 muscle
- as a product that contains calcium into their vein.

Ceftriaxone can be administered by intravenous infusion over at least 30 minutes or 60 minutes to reduce the potential risk of bilirubin encephalopathy (see section 4.3). The solution should be administered by deep intramuscular injection.

Dosages greater than 1g should be divided and injected at more than one site.

Intravenous doses of 50mg/kg or more in infants and children up to 12 years of age should be given as an injection directly into a vein or as a drip (intravenous infusion) over at least 30 minutes. The solution should be administered by deep intramuscular injection.

2. What you need to know before you take ceftriaxone

Older people
You may need a lower dose of ceftriaxone. The doses recommended in section 4.2 of the SmPC are the generally lowest doses for adults. In particularly severe cases, doses at the usual adult dose.

Children
The doses recommended in section 4.2 of the SmPC are the generally recommended doses in these indications. In particularly severe cases, doses at the usual adult dose.

Children with a body weight of 50kg or more should be given the usual adult dose.

Newborn babies, infants and children aged 15 days to 12 years with a body weight of less than 50kg:
- 50–80mg ceftriaxone for the kg of body weight of each child 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 4g once a day. If your daily dose is higher than 2g, you may receive it as a single dose once a day or as two separate doses.
- 50-80mg 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 to be no more than 50g/kg for each kg of the baby's weight.

Newborn babies (0-14 days)
- 20 – 50mg ceftriaxone for each kg of the baby's body weight once a day depending on the severity and type of infection.
- The maximum daily dose is not to be more than 50mg/kg for each kg of the baby's weight.

In patients with impaired renal function, there is no need to reduce the dosage of ceftriaxone. In patients with impaired renal function (creatinine clearance <10ml/min) the solution should not be given more than 24h after the renal function is improved (following the dialysis). Ceftriaxone is not removed by peritoneal or haemodialysis. Ceftriaxone is not removed by peritoneal dialysis

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

Doseage and Administration Information Only
Please refer to the Summary of Product Characteristics for further information.

Method of Administration
Intramuscular administration
Ceftriaxone 1g powder for solution for injection or infusion
Can be dissolved in 10ml of water for injections PhEur containing 165mg sodium (main component of cooking/ table salt) in each 2g vial. This is equivalent to 8.3% of the recommended maximum daily dietary intake of sodium for an adult.

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 and how well you are feeling. The blood and liver are working. The number of days or weeks that you have been given ceftriaxone will depend 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):
- 2g ceftriaxone once a day
- 1 to 2g once a day depending on the severity and type of infection

The baby is newborn (up to 28 days of age) and has certain blood infections
- your doctor will give you a higher dose up to 100mg for each kg of body weight to a maximum of 4g once a day.
- If your daily dose is higher than 2g, you may receive it as a single dose once a day or as two separate doses.

Adults, older people and children aged 12 years and over with a body weight of less than 50kg:
- 50–80mg 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 4g once a day. If your daily dose is higher than 2g, 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 50kg:
- 50-80mg 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 to be no more than 50mg/kg 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 during treatment.

If you accidentally receive more than your prescribed dose, contact your doctor.

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 label. The expiry date refers to the last day of that month.

The vials and bottles should not be stored above 25°C.

Keep the vial or bottle in the outer carton.

106653/12

2. How much ceftriaxone to use

Ceftriaxone should not be mixed in the same syringe with any drug other than 1% Lidocaine Injection BP

The use of freshly prepared solutions is recommended. For storage conditions of the reconstituted vial for IV administration because a precipitate can form.

For Intravenous injection, 1g ceftriaxone is dissolved in 10ml of Water for Injections. The injection should be administered over 5 minutes, directly into the vein or via the tubing of an intravenous infusion.

These approximate available volume and approximate displacement volume values are when reconstituted vial for IV administration and 30-90 minutes prior to surgery.

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, nausea, vomiting, the skin becomes very red, pain in muscle, and skin that is usually self-limiting. This occurs shortly after starting ceftriaxone treatment for infections with spirochetes such as syphilis.

Treatment with ceftriaxone, particularly in elderly patients with serious and persistent symptoms may rarely cause decreased consciousness, abnormal movements, agitation and convulsions.

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 diarrhea.
• 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 (granulocytes).
• Reduction in number of red blood cells (anaemia).
• Problems with the way your blood clots. The signs may include bruising easily and swelling and pain 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 (colitis). The signs include diarrhea, usually with blood and mucus, stomach pain and fever.
• Difficulty in breathing (bronchospasm).
• A lump (bump) which 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.

For information on the medicinal product, see section 6.3 of the SmPC.

Table: 2

<table>
<thead>
<tr>
<th>Reference number</th>
<th>Ceftriaxone 1g powder for solution for injection</th>
<th>Ceftriaxone 2g powder for solution for injection</th>
</tr>
</thead>
<tbody>
<tr>
<td>29861/0034</td>
<td>Ceftriaxone 1g powder for solution for injection</td>
<td>Ceftriaxone 2g powder for solution for injection</td>
</tr>
<tr>
<td>29861/0033</td>
<td>This is a service provided by the Royal National Institute of Blind People. Marketing Authorisation Holder: Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UR, UK. Manufacturer: C P Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UR, UK. This leaflet was last reviewed in 06/2022.</td>
<td></td>
</tr>
</tbody>
</table>

6. Contents of the pack and other information

What ceftriaxone contains
The active substance is ceftriaxone sodium. Each container contains the equivalent of 1g or 2g of ceftriaxone. The sodium content is approximately 82mg (3.5mmol) for the 1g vial and 165mg (7.2mmol) for the 2g bottle.

What ceftriaxone looks like and contents of the pack
Ceftriaxone is a white to pale yellow powder, which must be made into a solution before injection or infusion.

Ceftriaxone 1g is available in packs of 1, 5, 10, 25 or 50 vials. Not all pack sizes are marketed.

Ceftriaxone 2g is available in packs of 1 or 10 bottles. Not all pack sizes are marketed.

7. What happens if you take too much

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK Only)

Please be ready to give the following information:

PIL Information

What will happen if you miss a dose?

Incompatibilities

Based on literature reports, ceftriaxone is not compatible with amarantus, vancomycin, fluoroquinolones and aminoglycosides.

Do not use a solution which has become discoloured. Ceftriaxone sodium when dissolved in Water for Injections Ph Eur forms a pale yellow to amber solution.

Ceftriaxone is a white to pale yellow powder, which must be made into a solution before injection or infusion. For a missed dose.

If you get a severe skin 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 reactions (not known, frequency cannot be estimated from the available data)
If you have a severe allergic reaction, tell a doctor straight away.

Severe allergic reactions (not known, frequency cannot be estimated from the available data)
• 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 reactions (not known, frequency cannot be estimated from the available data)
If you have any further questions on the use of this medicine, ask your doctor or nurse.

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.

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, nausea, vomiting, the skin becomes very red, pain in muscle, and skin that is usually self-limiting. This occurs shortly after starting ceftriaxone treatment for infections with spirochetes such as syphilis.

Treatment with ceftriaxone, particularly in elderly patients with serious and persistent symptoms may rarely cause decreased consciousness, abnormal movements, agitation and convulsions.

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 diarrhea.
• 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 (granulocytes).
• Reduction in number of red blood cells (anaemia).
• Problems with the way your blood clots. The signs may include bruising easily and swelling and pain 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 (colitis). The signs include diarrhea, usually with blood and mucus, stomach pain and fever.
• Difficulty in breathing (bronchospasm).
• A lump (bump) which 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.