

## Package leaflet: Information for the patient

### **Ceftriaxone hameln 1 g powder for solution for injection/infusion** **Ceftriaxone hameln 2 g powder for solution for injection/infusion**

ceftriaxone

**Read this leaflet carefully 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 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.

#### **What is in this leaflet**

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

#### **1. What Ceftriaxone hameln is and what it is used for**

Ceftriaxone hameln 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 hameln 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 take Ceftriaxone hameln**

##### **Do not take Ceftriaxone hameln:**

- if you are allergic to ceftriaxone
- if 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;
- if you are allergic to lidocaine and you are to be given Ceftriaxone hameln as an injection into a muscle.

#### **Ceftriaxone hameln 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 and/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 taking Ceftriaxone hameln:

- 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,
- if you have ever had problems with your gut, in particular colitis (inflammation of the bowel),
- if you have liver or kidney problems (see section 4),
- 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 and cause weakness or breathlessness),
- if you are on a low sodium diet,
- 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 need a blood or urine test**

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

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 given Ceftriaxone hameln:

- if your child has recently been given or is to be given a product that contains calcium into their vein.

#### **Other medicines and Ceftriaxone hameln**

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 for advice before taking this medicine.

The doctor will consider the benefit of treating you with Ceftriaxone hameln against the risk to your baby.

### **Driving and using machines**

Ceftriaxone hameln 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 hameln contains sodium**

This medicine contains 83 mg sodium (main component of cooking/table salt) in each 1 g vial. This is equivalent to 4.15% of the recommended maximum daily dietary intake of sodium for an adult.

This medicine contains 166 mg sodium (main component of cooking/table salt) in each 2 g vial. This is equivalent to 8.30% of the recommended maximum daily dietary intake of sodium for an adult.

Preparing the medicine for administration – see the section “The following information is intended for health care professionals only” at the end of this package leaflet. The amount of sodium obtained from the diluent should be taken into account when calculating the total sodium content in the final product solution.

For detailed information on the sodium content of the solution used for dilution, please refer to the patient information leaflet for the diluent used.

## **3. How to take Ceftriaxone hameln**

Ceftriaxone hameln 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 hameln 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 on the correct dose of Ceftriaxone hameln 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 hameln depends on what sort of infection you have.

### **Adults, elderly patients 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 of Ceftriaxone hameln 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 of Ceftriaxone hameln 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.

### **Patients with liver and kidney problems**

You may be given a different dose to the usual dose. Your doctor will decide how much Ceftriaxone hameln you will need and will check you closely depending on the severity of the liver and kidney

disease.

**If you take 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 take 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 taking 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:

**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. (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 the 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 and/or being sick,
- pruritus (itching),
- pain or a burning feeling along the vein where Ceftriaxone hameln has been given. Pain where the injection has been given,
- 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),
- decreased consciousness, abnormal movements, agitation and convulsion, particularly in elderly patients with serious kidney or nervous system problems,
- 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-colored 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 hameln 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 HPRC Pharmacovigilance Website: [www.hpra.ie](http://www.hpra.ie)

By reporting side effects, you can help provide more information on the safety of this medicine.

**5. How to store Ceftriaxone hameln**

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 box and vial label after “EXP”. The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions.  
Store in the original package in order to protect from light.

Good practice principles indicate that solutions should be prepared immediately before use.

Shelf life after reconstitution/dilution:

Ceftriaxone hameln after reconstitution/dilution for intramuscular injection, intravenous injection and infusions is chemically and physically stable in all recommended solvents:

- for 6 hours at a temperature below 25°C,
- for 24 hours at 2°C to 8°C (in refrigerator).

The reconstituted product does not require protection from light.

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, unless the reconstitution/dilution has taken place in controlled and validated aseptic conditions.

Do not use this medicine if you notice any visible signs of deterioration.

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 hameln contains**

- The active substance is ceftriaxone. Each vial contains 1 g or 2 g of ceftriaxone (as ceftriaxone sodium).
- There are no other ingredients.

### **What Ceftriaxone hameln looks like and contents of the pack**

Ceftriaxone hameln is almost white or yellowish powder.

Ceftriaxone hameln is supplied in glass vial made of colourless glass of third hydrolytic class closed with a bromobutyl rubber stopper with aluminium seal or aluminium seal with plastic flip-off cap.

Each pack contains 10 vials.

### **Marketing Authorisation Holder**

hameln pharma gmbh  
Inselstraße 1  
31787 Hameln  
Germany

### **Manufacturer**

hameln rds s.r.o.  
Horná 36  
900 01 Modra  
Slovakia

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

Austria	Ceftriaxon hameln 1 g Pulver zur Herstellung einer Injektions-/Infusionslösung
	Ceftriaxon hameln 2 g Pulver zur Herstellung einer Injektions-/Infusionslösung

Belgium	Ceftriaxon hameln 1 g poeder voor oplossing voor injectie/infusie / Pulver zur Herstellung einer Injektions-/Infusionslösung / poudre pour solution injectable/pour perfusion Ceftriaxon hameln 2 g poeder voor oplossing voor injectie/infusie / Pulver zur Herstellung einer Injektions-/Infusionslösung / poudre pour solution injectable/pour perfusion
Czech Republic	Ceftriaxone hameln
Denmark	Ceftriaxon "hameln"
Finland	Ceftriaxon hameln 1 g injektio-/infuusiokuiva-aine, liuosta varten Ceftriaxon hameln 2 g injektio-/infuusiokuiva-aine, liuosta varten
Germany	Ceftriaxon hameln 1 g Pulver zur Herstellung einer Injektions-/Infusionslösung Ceftriaxon hameln 2 g Pulver zur Herstellung einer Injektions-/Infusionslösung
Ireland	Ceftriaxone hameln 1 g powder for solution for injection/infusion Ceftriaxone hameln 2 g powder for solution for injection/infusion
Italy	Ceftriaxone hameln
Netherlands	Ceftriaxon hameln 1 g poeder voor oplossing voor injectie/infusie Ceftriaxon hameln 2 g poeder voor oplossing voor injectie/infusie
Norway	Ceftriaxon hameln 1 g pulver til injeksjons-/infusjonsvæske, oppløsning Ceftriaxon hameln 2 g pulver til injeksjons-/infusjonsvæske, oppløsning
Slovakia	Ceftriaxone hameln 1 g prášok na injekčný/infúzny roztok Ceftriaxone hameln 2 g prášok na injekčný/infúzny roztok
Sweden	Ceftriaxon hameln 1 g Pulver till injektions-/infusionsvätska, lösning Ceftriaxon hameln 2 g Pulver till injektions-/infusionsvätska, lösning

**This leaflet was last revised in:**

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**The following information is intended for healthcare professionals only:**

Ceftriaxone hameln 1 g powder for solution for injection/infusion can be used for IM injection, slow IV injection and IV infusion.

Ceftriaxone hameln 2 g powder for solution for injection/infusion can be used for IM injection, slow IV injection and IV infusion.

### **Reconstitution**

After the solvent is added to the vial contents, the vial should be shaken until the powder dissolves; the solution should be clear after 1-2 minutes.

The solution after reconstitution may be colourless to yellow; the colour intensity depends on the concentration of ceftriaxone and diluent used.

For single use only. Any unused solution should be discarded.

### **Method of administration**

Ceftriaxone hameln can be administered by intravenous infusion over at least 30 minutes (preferred route) or by slow intravenous injection over 5 minutes, or by deep intramuscular injection. Intravenous intermittent injection should be given over 5 minutes preferably in larger veins. Intravenous doses of 50 mg/kg bw or more in infants and children up to 12 years of age should be given by infusion. In neonates, intravenous doses should be given over 60 minutes to reduce the potential risk of bilirubin encephalopathy. Intramuscular injections should be injected well within the bulk of a relatively large muscle and no more than 1 g should be injected at one site. Intramuscular administration should be considered when the intravenous route is not possible or less appropriate for the patient.

For doses greater than 2 g, intravenous administration should be used.

Calcium-containing diluents, such as Ringer's solution or Hartmann's solution, should not be used to reconstitute Ceftriaxone hameln vials or to further dilute a reconstituted vial for intravenous

administration because a precipitate can form. Precipitation of ceftriaxone-calcium salt can also occur when ceftriaxone is mixed with calcium-containing solutions in the same intravenous administration line. Therefore, ceftriaxone and calcium-containing solutions must not be mixed or administered simultaneously.

However, to avoid precipitation, in patients older than 28 days of age ceftriaxone and calcium-containing solutions may be administered sequentially one after another if infusion lines at different sites are used or if the infusion lines are replaced or thoroughly flushed between infusions with physiological salt-solution. In patients requiring continuous infusion with calcium-containing total parenteral nutrition (TPN) solutions, healthcare professionals may wish to consider the use of alternative antibacterial treatments which do not carry a similar risk of precipitation. If the use of ceftriaxone is considered necessary in patients requiring continuous parenteral nutrition, TPN solutions and ceftriaxone can be administered simultaneously, albeit via different infusion lines at different sites. Alternatively, infusion of TPN solution could be stopped for the period of ceftriaxone infusion and the infusion lines flushed between solutions.

Prior to administration, the solution should be inspected for clearness and insoluble matter.

Following administration, it is recommended that the intravenous line is flushed with infusion fluid to ensure administration of the complete dose.

### **Intramuscular injection**

The product should be diluted with an appropriate volume of

- water for injection,
- lidocaine 10 mg/ml (1%) solution,
- sodium chloride 9 mg/ml (0.9%) solution.

Dose	Volume of solvent	Approximate solution concentration
1 g	3.5 ml	238 mg/ml
2 g	7 ml	238 mg/ml

The drug should be administered by deep intramuscular injection.

The drug should not be mixed in the same syringe with any drug other than lidocaine hydrochloride 10 mg/ml (1%) solution.

Do not administer intravenous solution of the product with lidocaine.

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

For doses greater than 2 g, intravenous administration should be used.

### **Intravenous injection (5 minutes)**

The contents of the vial should be dissolved with one of the following liquid for injection:

- water for injection,
- sodium chloride 9 mg/ml (0.9%) solution,
- glucose 50 mg/ml (5%) solution.

Dose	Volume of solvent	Approximate solution concentration
1 g	10 ml	93.5 mg/ml
2 g	20 ml	93.5 mg/ml

Do not administer intravenous solution of the product with lidocaine.

### **Intravenous infusion (at least 30 minutes)**

In order to prepare intravenous infusion solutions of ceftriaxone at concentrations of 10 mg/ml to 50 mg/ml, the powder should be dissolved in 10 ml of one of the following solutions:

- sodium chloride 9 mg/ml (0.9%) solution,
- glucose 50 mg/ml (5%) solution,
- glucose 50 mg/ml (5%) solution with sodium chloride 9 mg/ml (0.9%) solution 1:1,
- glucose 50 mg/ml (5%) solution with sodium chloride 9 mg/ml (0.9%) solution 2:1.

The solution thus obtained should be further diluted with the same solution as used for dissolution.

Dose	Total volume of solvent	Approximate solution concentration
1 g	20 ml	50 mg/ml
1 g	25 ml	40 mg/ml
1 g	100 ml	10 mg/ml
2 g	40 ml	50 mg/ml
2 g	50 ml	40 mg/ml
2 g	200 ml	10 mg/ml

Do not administer intravenous solution of the product with lidocaine.