Package leaflet: information for the patient

Cefotaxime hameln 1 g powder for solution for injection/infusion
Cefotaxime hameln 2 g powder for solution for injection/infusion

cefotaxime

Read all of 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 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Cefotaxime hameln is and what it is used for

Cefotaxime hameln is an antibiotic, i.e. a medicine which is used for the treatment of bacterial infections of:
the lungs (pneumonia)
the skin and soft tissue
the urinary tract
the genitals (including gonorrhoea)
the heart valves (endocarditis)
the membranes covering the brain (meningitis)
the abdomen
the blood (so called 'bacteraemia')

Furthermore cefotaxime is used to treat the Lyme disease (borreliosis, an infection primarily caused by tick bites, e.g. relapsing fever).
Cefotaxime can also be used before and during surgery in order to prevent possible infections.

2. What you need to know before you are given Cefotaxime hameln

You must not be given Cefotaxime hameln if you:
- are allergic (hypersensitive) to cefotaxime or to any cephalosporin antibiotics or any of the other ingredients of this medicine (listed in section 6).
- have ever had a severe allergic (hypersensitive) reaction to any other type of beta-lactam antibiotic (penicillins, monobactams and carbapenems).
- have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking cefotaxime or other cephalosporins.

Do not have this medicine if any of the above applies to you. If you are not sure, talk to your doctor or nurse before having Cefotaxime hameln.

Warnings and precautions
Talk to your doctor or nurse before using Cefotaxime hameln if:
- If you have allergic reactions. If you have had any allergic reactions to other antibiotics such as penicillin, you may be allergic to Cefotaxime hameln. If an allergic reaction occurs, treatment should be stopped.
- if you suffer from severe, persistent diarrhoea during or after treatment with Cefotaxime hameln. In this case contact your doctor immediately. Do not take any anti-diarrhoea medicine without consulting your doctor.
- if you have a widespread rash with blisters and peeling skin. These may be signs of Stevens-Johnson syndrome or toxic epidermal necrolysis. Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS), acute generalized exanthematous pustulosis (AGEP) have been reported in association with cefotaxime treatment. Stop using cefotaxime and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.
- If you have kidney problems.
- if you experience e.g. impairment of consciousness, abnormal movements and cramps after being given this medicine.
- if you are on a low salt diet. Then the sodium content of this product must be taken into account.

Cefotaxime hameln is sometimes mixed with lidocaine. In this case talk to your doctor or nurse if:
- You are allergic to lidocaine or other local anaesthetics.
- Your child is younger than 30 months.
- You have heart disease, problems with your heartbeat or severe heart failure.

If any of these apply to you, your doctor may want to change your treatment or give you special advice. If you are given this medicine over a longer period, your doctor will take additional care and check your blood for possible changes. Also the overgrowth of bacteria that are unsusceptible to cefotaxime must be examined regularly in this case.

Other medicines and Cefotaxime hameln
Tell your doctor or pharmacist if you are taking any of the following, have recently taken or might take any other medicines. This includes medicines you buy without a prescription, including herbal medicines.
This is because Cefotaxime hameln can affect the way some other medicines work. Also some medicines can affect the way Cefotaxime hameln works.

In particular, check with your doctor if you are taking any of the following:
- Aminoglycoside antibiotics - including gentamicin, streptomicin, neomycin, kanamycin, amikacin or tobramycin
- Water tablets (diuretics) such as furosemide, etacrynic acid
- Probenecid – used for gout

Tests
If you require any tests (such as blood, urine or diagnostic), while taking this medicine, please make sure your doctor knows that you are taking Cefotaxime hameln.

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.

Your doctor will only give you cefotaxime during pregnancy after consideration of benefits and risks.

Cefotaxime passes into breast milk in small amounts. Therefore it should not be used during breast-feeding.

Driving and using machines
You may start to move abnormally, suffer from sudden involuntary muscle contractions, dizziness or

feel less alert. If this happens, do not drive or use any tools or machines.

Cefotaxime hameln contains sodium

1 g vial: This medicine contains 48 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 2.4% of the recommended maximum daily dietary intake of sodium for an adult.

2 g vial: This medicine contains 96 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 4.8% of the recommended maximum daily dietary intake of sodium for an adult.

3. How Cefotaxime hameln is given

Administration
Cefotaxime hameln is always administered by healthcare personnel. This medicine is first dissolved in sterile water or another suitable solution. The solution may be given as an injection or through a tube (infusion) into a vein, for certain infections it may also be injected into a muscle.

Dosage
Adults and adolescents over 12 years
You usually receive 2 to 6 g cefotaxime daily. The daily dose should be divided in two single doses every 12 hours. The dosage may be varied according to the severity of your infection and your condition:
- Common infections in presence (or suspicion) of sensitive bacteria: 1 g every 12 hours (i.e. total daily dose of 2 g).
- Infections in presence (or suspicion) of several sensitive or moderately sensitive bacteria: 1 – 2 g every 12 hours (i.e. total daily dose of 2 – 4 g).
- Severe infections or for infections that cannot be localised: 2 – 3 g as a single dose every 6 to 8 hours (i.e. a maximum daily dose of 12 g).

Newborns (0 – 28 days), infants and children up to 12 years of age
Children: The usual dosage range is 100-150 mg/kg/day in 2 to 4 divided doses. However, in very severe infections doses of up to 200 mg/kg/day may be required.
Neonates: The recommended dosage is 50 mg/kg/day in 2 to 4 divided doses. In severe infections 150-200 mg/kg/day, in divided doses, have been given.

Elderly
Provided that your kidney and liver function is normal, no dosage adjustment is required.

People with kidney and/or liver problems
If you have problems with your kidneys and/or liver, you may be given a lower dose. You may need to have blood tests to check that you are getting the dose you need. Your doctor will decide on the dose.

Other special recommendations

Gonorrhoea
You will receive a single injection of 0.5 – 1 g Cefotaxime hameln as an injection into a muscle or a vein for treatment of gonorrhoea.

Bacterial meningitis
Adults receive a daily dose of 6 to 12 g cefotaxime divided into equal doses every 6 to 8 hours.
Children receive 150 to 200 mg per kg body weight divided into equal doses every 6 to 8 hours.
Newborns: 0-7 days old babies receive 50 mg per kg body weight every 12 hours, 7 – 28 days old infants every 8 hours.

Prevention of infections (perioperative prophylaxis)

You may be given between 1 g and 2 g cefotaxime before an operation for the prevention of possible infections. If the operation lasts longer than 90 minutes, you may be given an additional dose preventively.

Infections inside the abdomen
You should be given a combination of cefotaxime and an antibiotic acting against 'anaerobic' bacteria.

Treatment duration
Your treatment duration depends on the severity of your infection as well as on your recovery from your illness. You will usually continue to be given the medicine for at least 2 to 3 days after you have started to recover from your illness. Treatment over at least 10 days is necessary in infections caused by the bacterium Streptococcus pyogenes.

Method of administration
Cefotaxime hameln 1 g powder for solution for injection/infusion may be administered **intramuscularly** (by slow injection) or **intravenously** (by slow injection or infusion).

Cefotaxime hameln 2 g powder for solution for injection/infusion may be administered **intravenously** (by slow injection or infusion).

For more details on posology and method of preparation of the drug for administration, see the 'The following information is intended for healthcare professionals only' section at the end of this leaflet.

If you are given more Cefotaxime hameln than you should
Tell your doctor or nurse if you think you have been given too much Cefotaxime hameln.

If a dose of Cefotaxime hameln has been forgotten
Please contact your doctor immediately. A double dose must not be given to make up for a forgotten dose. A forgotten dose should be given only if the time until the next regular dose is long enough.

If you stop using Cefotaxime hameln
Low dosage, irregular administration or stopping treatment too early can compromise the outcome of the treatment or lead to a relapse, whose treatment is more difficult. Please follow the instructions of your doctor.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking cefotaxime and tell your doctor immediately if you notice any of the following symptoms:
• Reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis).
• Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).
• A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalised exanthematous pustulosis).

You must contact your doctor immediately if you notice any of the following:

Uncommon side effects (may affect up to 1 in 100 people)

• Increased tendency to bleed or bruise more easily caused by a fall in the number of blood platelets (thrombocytopenia), fever, sore throat or mouth ulcers due to infections caused by a low level of white blood cells (leucopenia) or high level of a specific type of white blood cells (eosinophilia).

Not known: frequency cannot be estimated from the available data
• Inflammation of the bowels, called colitis (or antibiotic-associated colitis), causing severe long-lasting watery or bloody diarrhoea with stomach cramps and fever
• Serious blood problems, including changes in the numbers of some white blood cells (which may cause frequent infections, fever, severe chills, sore throat, or mouth ulcers)
• Damage to red blood cells (causing tiredness, being short of breath or looking pale)
• Severe allergic reactions with symptoms such as swelling of the lips, tongue, face and neck, sudden difficulty in breathing, speaking and swallowing;
• Headache, dizziness, convulsions (fits) (these may be symptoms of a brain disorder called encephalopathy)
• Changes in heartbeat (rhythm or rate), after a very quick injection into a vein
• Yellow skin and eyes, loss of appetite, light-coloured urine caused by inflammation of the liver.
• Increased or reduced urine output, or traces of blood in your urine, sometimes with swollen limbs and / or flank pain caused by kidney problems
• For intramuscular injection: combination with lidocaine can cause systemic reactions

Other possible side effects:

Very common: may affect more than 1 in 10 people
- Intramuscular injection may be painful

Uncommon: may affect up to 1 in 100 people
- People being treated for infections with bacteria called spirochetes often show symptoms like fever and shivering which are described as ‘Herxheimer reaction’ and indicate the effectiveness of the therapy.
- Changes in the results of blood tests that check how the liver and kidneys are working
- Fever
- Allergic reactions such as skin rash (nettle rash), itchy skin
- Painful swelling and inflammation where the injection is given into a vein
- Soft stools or diarrhoea
- Convulsions

Not known: frequency cannot be estimated from the available data
- Feeling sick (nausea) and being sick (vomiting)
- Pain in your stomach (abdomen)

Your doctor may want to perform tests during your treatment to measure any changes.

Reporting side effects
If you get any side effects, talk to your doctor or pharmacist. 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 Cefotaxime hameln

Keep this medicine out of the sight and reach of children.

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

The reconstituted solution is chemically and physically stable:
- at a temperature of 2°C to 8°C for 24 hours;
- at a temperature below 25°C for 2 hours.
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.

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.

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 Cefotaxime hameln contains
- The active substance is cefotaxime.
  Each vial contains 1 or 2 g of cefotaxime as cefotaxime sodium.
- This medicine does not contain excipients.

What Cefotaxime hameln looks like and contents of the pack
The medicine is a white or slightly yellow powder. Glass vials closed with bromobutyl rubber closures and sealed with aluminium caps and aluminium seal or an aluminium cap with a flip-top plastic cover.

A package contains 10 vials.

Marketing Authorisation Holder
hameln pharma gmbh
Inselstraße 1
31787 Hameln
Germany

Manufacturer
hameln rds s.r.o.
Horna 36
900 01 Modra
Slovakia

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

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

Czech republic	Cefotaxime hameln
Denmark	Cefotaxim “hameln”
Finland	Cefotaxim hameln, 1 g injektio-/infuusiokuiva-aine, liuosta varten Cefotaxim hameln, 2 g injektio-/infuusiokuiva-aine, liuosta varten
Germany	Cefotaxim hameln 1 g Pulver zur Herstellung einer Injektions-/Infusionslösung Cefotaxim hameln 2 g Pulver zur Herstellung einer Injektions-/Infusionslösung
Ireland	Cefotaxime hameln 1 g powder for solution for injection/infusion Cefotaxime hameln 2 g powder for solution for injection/infusion
Italy	Cefotaxima hameln
Netherland	Cefotaxim hameln 1 g poeder voor oplossing voor injectie/infusie Cefotaxim hameln 2 g poeder voor oplossing voor injectie/infusie
Norway	Cefotaxim hameln
Slovakia	Cefotaxime hameln 1 g prášok na injekčný/infúzny roztok Cefotaxime hameln 2 g prášok na injekčný/infúzny roztok
Sweden	Cefotaxim hameln Pulver till injektions-/infusionsvätska, lösning 1 g, Cefotaxim hameln Pulver till injektions-/infusionsvätska, lösning 2 g

This leaflet was last revised in April 2025

The following information is intended for healthcare professionals only:

Methods of administration
Cefotaxime hameln 1 g powder for solution for injection/infusion may be administered by slow **intramuscular injection, intravenous injection or intravenous infusion.**
Cefotaxime hameln 2 g powder for solution for injection/infusion may be administered by slow **intravenous injection or 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 solution of the reconstituted product should be inspected visually for clearness and particulate matter prior to administration. Only clear solution free from particles or precipitates should be used. If it is cloudy or it contains particulate matter, the solution is not suitable for use.

For single use only.

Cefotaxime solutions must not be administered intravenously with lidocaine solution.

Preparation of solution for injection and infusion and methods of administration

Intravenous injection (given from 3 to 5 minutes)
For intravenous injection, 1 g cefotaxime should be dissolved in 4 ml of water for injections, 9 mg/ml (0.9%) sodium chloride solution for injection or 50 mg/ml (5%) glucose solution for injection and 2 g cefotaxime should be dissolved in 10 ml of water for injections 9 mg/ml (0.9%) sodium chloride solution for injection or 50 mg/ml (5%) glucose solution for injection and should be injected over 3 – 5 minutes.

Intravenous infusion (given from 20 to 60 minutes)
In order to prepare solutions of cefotaxime for intravenous infusion, the powder is dissolved in water for injection (in the same way as for intravenous injections).
The solution thus obtained should be further diluted with one of the following solutions:
9 mg/ml (0.9%) sodium chloride solution,
50 mg/ml (5%) glucose solution,

50 mg/ml (5%) glucose solution with 9 mg/ml (0.9%) sodium chloride solution 1:1,
50 mg/ml (5%) glucose solution with 9 mg/ml (0.9%) sodium chloride solution 2:1,
Ringer's solution,
Compound Sodium Lactate Injection (Ringer-lactate Injection).

Antibiotic content per vial	**Solvent volume**	
	Intravenous injection	**Intravenous infusion**
1 g	10 ml	40–100 ml
2 g	10 ml	40–100 ml

In order to avoid any risk of infection, the reconstitution of the solution for infusion should be done in close aseptic conditions. Do not postpone the infusion after the reconstitution of the solution.
For short intravenous infusion: Following reconstitution, the solution should be administered over 20 minutes.
For long lasting intravenous infusion: Following reconstitution, the solution should be administered over 50 – 60 minutes.

Intramuscular injection (recommended only for 1 g vials)
The contents of 1 g vial should be dissolved in 4 ml of water for injection, 9 mg/ml (0.9%) sodium chloride solution or 10 mg/ml (1%) lidocaine solution.

Antibiotic content per vial	**Solvent volume**
	Intramuscular injection
1 g	4 ml
2 g	-

The intramuscular administration is restricted to exceptional clinical situations (e.g. gonorrhoea) and should undergo a benefit-risk assessment. It is recommended that not more than 4 ml are injected unilaterally. If the daily dose exceeds 2 g cefotaxime or if cefotaxime is injected more frequently than twice per day, the intravenous route is recommended.

For intramuscular administration, 1 g cefotaxime is dissolved in 4 ml of water for injections. To prevent pain from the injection, a 10 mg/ml (1%) lidocaine hydrochloride solution may be used alternatively (only for adults). The solution should be administered by deep intramuscular injection. Solutions in lidocaine must not be administered intravenously. The product information of the chosen lidocaine containing solution must be regarded.
Cefotaxime reconstituted with lidocaine should not be administrated to children less than 30 months of age.

In the case of severe infections, intramuscular injection is not recommended.

Incompatibilities
Aminoglycosides are incompatible with cephalosporins in parenteral mixtures.
This medicine must not be mixed with other medicinal products except those mentioned above.