

Cefuroxime 1.5 g powder for solution for injection/infusion

cefuroxime

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 or nurse.
- 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 Cefuroxime is and what it is used for
2. What you need to know before you are given Cefuroxime
3. How Cefuroxime is given
4. Possible side effects
5. How to store Cefuroxime
6. Contents of the pack and other information

1. What Cefuroxime is and what it is used for

Cefuroxime is an antibiotic used in adults and children. It works by killing bacteria that cause infections. It belongs to a group of medicines called *cephalosporins*.

Cefuroxime is used to treat infections of:

- the lungs or chest
- the urinary tract
- the skin and soft tissue
- the abdomen.

Cefuroxime is also used:

- to prevent infections during surgery.

Your doctor may test the type of bacteria causing your infection and monitor whether the bacteria are sensitive to Cefuroxime during your treatment.

2. What you need to know before you are given Cefuroxime

You must not be given Cefuroxime if you:

- are allergic 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 betalactam antibiotic (penicillins, monobactams and carbapenems).
- have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after treatment with Cefuroxime or any other cephalosporin antibiotics.

Tell your doctor before you start on Cefuroxime if you think that this applies to you. You must not be given Cefuroxime.

Warnings and precautions

Take special care with Cefuroxime

Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with cefuroxime treatment. Seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

You must look out for certain symptoms such as allergic reactions, skin rashes, gastrointestinal disorders such as diarrhoea or fungal infections while you are being given Cefuroxime. This will reduce the risk of possible problems. See ('Conditions you need to look out for') in section 4. If you have had any allergic reaction to other antibiotics such as penicillin, you may also be allergic to Cefuroxime.

If you need a blood or urine test

Cefuroxime can affect the results of urine or blood 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 Cefuroxime.

Other medicines and Cefuroxime

Tell your doctor if you are taking any other medicines, if you've started taking any recently or you start taking new ones. This includes medicines you can obtain without a prescription.

Some medicines may affect how Cefuroxime works or make it more likely that you'll have side effects. These include:

- **aminoglycoside-type antibiotics**
- **water tablets** (diuretics), such as furosemide
- **probenecid**
- **oral anticoagulants.**

Tell your doctor if this applies to you. You may need extra check-ups to monitor your renal function while you are taking Cefuroxime.

Contraceptive pills

Cefuroxime may reduce the effectiveness of the contraceptive pill. If you are taking the contraceptive pill while you are being treated with Cefuroxime you also need to use a **barrier method of contraception** (such as a condom). Ask your doctor for advice.

Pregnancy, breast-feeding and fertility

Tell your doctor before you are given Cefuroxime:

- if you are pregnant, think you might be pregnant or are planning to become pregnant
- if you are breastfeeding

Your doctor will consider the benefit of treating you with Cefuroxime against the risk to your baby.

Driving and using machines

Don't drive or use machines if you do not feel well.

Cefuroxime contains sodium

You need to take this into account if you are on a controlled sodium diet.

This medicine contains 40.5 mg sodium (main component of cooking/table salt) per 750 mg dose and 81 mg sodium per 1.500 mg dose, respectively. This is equivalent to 2.03% and 4.05% of the recommended maximum daily dietary intake of sodium for an adult.

3. How Cefuroxime is given

Cefuroxime 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.

Cefuroxime can be administered as a suspension via intramuscular injection. Not more than 750 mg cefuroxime should be injected at one site.

The usual dose

The correct dose of Cefuroxime for you will be decided by your doctor and depends on: the severity and type of infection, whether you are on any other antibiotics; your weight and age; how well your kidneys are working.

Newborn babies (0 - 3 weeks)

For every 1 kg the baby weighs, they'll be given 30 to 100 mg Cefuroxime per day divided in two or three doses.

Babies (over 3 weeks) and children

For every 1 kg the baby or child weighs, they'll be given 30 to 100 mg of Cefuroxime per day divided in three or four doses.

Adults and adolescents

750 mg to 1.5 g of Cefuroxime two, three or four times daily. Maximum dose: 6 g per day.

Patients with kidney problems

If you have a kidney problem, your doctor may change your dose.

Talk to your doctor if this applies to you.

4. Possible side effects

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

Conditions you need to look out for

A small number of people taking Cefuroxime get an allergic reaction or potentially serious skin reaction. Symptoms of these reactions include:

- **severe allergic reaction.** Signs include **raised and itchy rash, swelling,** sometimes of the face or mouth causing **difficulty in breathing.**
- **skin rash,** which may **blister,** and looks like **small targets** (central dark spot surrounded by a paler area, with a dark ring around the edge).
- **a widespread rash with blisters and peeling skin.** (These may be signs of *Stevens-Johnson syndrome* or *toxic epidermal necrolysis*).
- **widespread rash, high body temperature and enlarged lymph nodes** (DRESS syndrome or drug hypersensitivity syndrome).
- **chest pain** in the context of **allergic reactions,** which may be a symptom of **allergy triggered cardiac infarction** (*Kounis syndrome*).

Other symptoms you need to be aware of while taking Cefuroxime include:

- **fungal infections** on rare occasions, medicines like Cefuroxime can cause an overgrowth of yeast (*Candida*) in the body which can lead to fungal infections (such as thrush). This side effect is more likely if you take Cefuroxime for a long time.
- **severe diarrhoea** (*Pseudomembranous colitis*). Medicines like Cefuroxime can cause inflammation of the colon (large intestine), causing severe diarrhoea, usually with blood and mucus, stomach pain, fever.

Contact a doctor or nurse immediately if you get any of these symptoms.

Common side effects

These may affect **up to 1 in 10 people:**

- injection site pain, swelling and redness along a vein.

Tell your doctor if any of these are troubling you.

Common side effects that may show up in blood tests:

- increases in substances (*enzymes*) produced by the liver
- changes in your white blood cell count (*neutropenia* or *eosinophilia*)
- low levels of red blood cells (*anaemia*).

Uncommon side effects

These may affect **up to 1 in 100 people:**

- skin rash, itchy, bumpy rash (*hives*)
- diarrhoea, nausea, stomach pain

Tell your doctor if you get any of these.

Uncommon side effects that may show up in blood tests:

- low levels of white blood cells (*leucopenia*)
- increase in bilirubin (a substance produced by the liver)
- positive Coomb's test.



The following information is intended for healthcare professionals only:

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Instructions for reconstitution

Addition volumes and solution concentrations, which may be useful when fractional doses are required.

Additional volumes and concentrations, which may be useful when fractional doses are required			
Routes of administration	Physical State	Amount of water to be added (mL)	Approximate cefuroxime concentration (mg/mL)**
intramuscular	suspension	6 mL	216
intravenous bolus	solution	at least 15 mL	94
intravenous infusion	solution	at least 15 mL*	94

* Reconstituted solution to be added to 50 or 100 mL of compatible infusion fluid (see information on compatibility, below)

** The resulting volume of the solution of cefuroxime in reconstitution medium is increased due the displacement factor of the drug substance resulting in the listed concentrations in mg/mL.

Other side effects

Other side effects have occurred in a very small number of people but their exact frequency is unknown:

- fungal infections
- high temperature (*fever*)
- allergic reactions
- inflammation of the colon (large intestine), causing diarrhoea, usually with blood and mucus, stomach pain
- inflammation in the kidney and blood vessels
- red blood cells destroyed too quickly (*haemolytic anaemia*)
- skin rash, which may blister, and looks like small targets (central dark spot surrounded by a paler area, with a dark ring around the edge) *erythema multiformae*.

Tell your doctor if you get any of these.

Side effects that may show up in blood tests:

- decrease in number of blood platelets (cells that help blood to clot - *thrombocytopenia*)
- increase in levels of urea nitrogen and serum creatinine in the blood.

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 the Yellow Card Scheme at: 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 Cefuroxime

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

Do not use this medicine after the expiry date shown on the pack 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 original packaging in order to protect from light.

After reconstitution and dilution:

The reconstituted product is chemically and physically stable:

- at 2°C to 8°C - for 24 hours for all the administration routes;
- below 25°C
 - for 12 hours for intramuscular injections
 - for 8 hours for intravenous injections
 - for 5 hours for intravenous infusion.

The reconstituted and diluted products do not require protection from light.

From a microbiological point of view, unless the method of reconstitution and dilution precludes the risk of contamination, the product should be used immediately.

If not used immediately, in use storage times and conditions are the responsibility of the user.

Do not throw away any medicines via wastewater or household waste. Your doctor or nurse will dispose of any medicine that is no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Cefuroxime contains

- The active substance is cefuroxime. Each vial contains 1.5 g of cefuroxime (as cefuroxime sodium).
- There are no other ingredients.

What Cefuroxime looks like and contents of the pack

Cefuroxime is a white or almost white powder filled in glass vial (20 mL) with a bromobutyl rubber stopper, aluminium cap or aluminium cap with a plastic flip-off lid. Pack contains 10 vials.

Other formats:

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:

Product Name	Reference Number
Cefuroxime 1.5 g powder for solution for injection/infusion	01502/0155

This is a service provided by the Royal National Institute of Blind People.

Marketing Authorisation Holder

hameln pharma ltd
Nexus, Gloucester Business Park
Gloucester, GL3 4AG
United Kingdom

Manufacturer

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Horna 36
900 01 Modra, Slovakia

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Compatibility

Cefuroxime sodium is compatible with the following infusion fluids:

- 0.9% sodium chloride;
- 5% glucose solution;
- 5% glucose and 0.9% sodium chloride. 1:1;
- 5% glucose and 0.9% sodium chloride. 2:1;
- Ringer solution;
- Lactated Ringer's solution;
- Heparin (10 or 50 IU/mL) in 0.9% sodium chloride;
- Potassium chloride (10 or 40 mEq/L) in 0.9% sodium chloride;
- Water for injection;
- 1% lidocaine solution.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.