

Package leaflet: Information for the user

Cefuroxime 750mg & 1.5g powder for solution for injection or infusion cefuroxime sodium

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

1. What Cefuroxime Injection/Infusion is and what it is used for

Cefuroxime Injection/Infusion 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 Injection/Infusion is used to treat infections of:

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

Cefuroxime Injection/Infusion 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 Injection/Infusion during your treatment.

2. What you need to know before you are given Cefuroxime Injection/Infusion

You must not be given Cefuroxime Injection/Infusion

- if you are allergic to any cephalosporin antibiotics or any of the other ingredients of Cefuroxime Injection/Infusion (listed in section 6).
- if you have ever had a severe allergic (*hypersensitive*) reaction to any other type of betalactam antibiotic (penicillins, monobactams and carbapenems).
- if you 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 Injection/Infusion if you think that this applies to you. You must not be given Cefuroxime Injection/Infusion.

Take special care with Cefuroxime Injection/Infusion

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.

Warnings and precautions

Talk to your doctor or nurse before you are given Cefuroxime Injection/Infusion.

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 Injection/Infusion. 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 Injection/Infusion.

If you need a blood or urine test

Cefuroxime Injection/Infusion 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 Injection/Infusion.

Other medicines and Cefuroxime Injection/Infusion

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines you can obtain without a prescription.

Some medicines may affect how Cefuroxime Injection/Infusion 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 Injection/Infusion.

Contraceptive pills

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

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 you are given this medicine.

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

Driving and using machines

Cefuroxime Injection/Infusion should not affect your ability to drive or use machines.

Cefuroxime Injection/Infusion 750mg contains 40.6mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 2% of the recommended maximum daily dietary intake of sodium for an adult.

Cefuroxime Injection/Infusion 1.5 g contains 81.3mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 4% of the recommended maximum daily dietary intake of sodium for an adult.

3. How you are given Cefuroxime Injection/Infusion

Cefuroxime Injection/Infusion 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.

The recommended dose

The correct dose of Cefuroxime Injection/Infusion 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, and how well your kidneys are working.

Use in adults and adolescents:

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

Use in 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 Injection/Infusion per day divided in three or four doses.

Use in newborn babies (0 -3 weeks):

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

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.

If you are given more Cefuroxime Injection/Infusion than you should receive

It is unlikely that you will be given too much, but if you think that you have been given too much Cefuroxime Injection/Infusion, tell your doctor, pharmacist or nurse immediately. Signs might include fits (convulsions).

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. All medicines can cause allergic reactions, although serious allergic reactions are very rare.

Conditions you need to look out for

A small number of people taking Cefuroxime Injection/Infusion 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 Injection/Infusion include:

- **fungal infections** on rare occasions, medicines like Cefuroxime Injection/Infusion 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 Injection/Infusion for a long time.
 - **severe diarrhoea (*Pseudomembranous colitis*)**. Medicines like Cefuroxime Injection/Infusion 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.**

Other side effects have also been reported:

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

- skin rash, itchy, bumpy rash (hives)
- diarrhoea, nausea, stomach pain
- temporary yellowing of the skin and whites of the eyes which usually return to normal after treatment (due to an increase in a substance made in the liver called bilirubin)

→ 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 Coombs test.

Frequency not known (frequency cannot be estimated from the available data):

- high temperature (fever), a sore throat or other signs of an infection
- 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 multiforme)
- encephalopathy (non-inflammatory brain disease)
- convulsions
- myoclonus (muscle-twitching)

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, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: 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 Injection/Infusion

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

Cefuroxime Injection/Infusion is for use in hospital only and the doctor or nurse will make up your medicine.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Do not store above 25 °C. Keep the vial in the outer carton in order to protect from light.

After reconstitution: From a microbiological point of view, the medicine 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 reconstitution has taken place in controlled and validated aseptic conditions.

For single use only. Discard any unused contents.

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 protect the environment.

6. Contents of the pack and other information

What Cefuroxime Injection/Infusion contains

The active substance is cefuroxime (as cefuroxime sodium).

Each 750 mg vial contains 750 mg cefuroxime (as cefuroxime sodium). Each 1.5 g vial contains 1.5 g cefuroxime (as cefuroxime sodium).

There are no other ingredients.

What Cefuroxime Injection/Infusion looks like and contents of the pack

Cefuroxime Injection/Infusion is contained in glass vials with rubber stoppers. Pack sizes of 5, 10, 50 or 100 vials for Cefuroxime 750 mg and 1, 10 or 50 vials for Cefuroxime 1.5 g.

Vials contain an off-white to slightly yellow powder which will be made up with Water for Injections or other recommended diluting solution. When made up for injection into a muscle, it becomes off-white and opaque. When made up for injection into a vein, it may be yellowish.

Not all pack sizes may be marketed.

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The following information is intended for healthcare professionals only:

Cefuroxime 750 mg and 1.5 g powder for solution for injection or infusion

Instructions for reconstitution

Additional volumes and solution/suspension concentrations, which may be useful when fractional doses are required.

Vial size	Route of administration	Amount of water to be added (mL)	Approximate cefuroxime concentration (mg/mL)**	Resulting product
750 mg	intramuscular	3 mL	216	Suspension
	intravenous bolus	at least 6 mL	116	Solution
	intravenous infusion	at least 6 mL*	116	Solution
1.5 g	intramuscular	6 mL	216	Suspension
	intravenous bolus	At least 15 mL	94	Solution
	intravenous infusion	15 mL*	94	Solution

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

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

As for all parenteral medicinal products, inspect the reconstituted solution or suspension visually for particulate matter and discoloration prior to administration.

Intramuscular injection: After addition of the specified amount of diluent for intramuscular injection, a suspension is formed.

Intravenous bolus injection or intravenous infusion: The solution should only be used if the solution is clear and practically free from particles.

Solutions and suspensions range in colour from clear to yellow coloured depending on concentration, diluent and storage conditions used. When made up for intramuscular use, it becomes off-white and opaque. When made up for intravenous administration, it may be yellowish.

Compatibility

1.5 g cefuroxime constituted with 15 mL Water for Injection may be added to metronidazole injection (500 mg/100 mL).

1.5 g cefuroxime is compatible with azlocillin 1 g (in 15 mL) or 5 g (in 50 mL).

Cefuroxime (5 mg/mL) in 5% w/v or 10% w/v xylitol injection may be used for intravenous use only.

Cefuroxime sodium is compatible with aqueous solutions containing up to 1% lidocaine hydrochloride. This should only be administered intramuscularly.

Cefuroxime sodium is compatible with the following infusion fluids:

- 0.9% w/v Sodium Chloride Injection BP
- 5% Dextrose Injection BP
- 0.18% w/v Sodium Chloride plus 4% Dextrose Injection BP

- 5% Dextrose and 0.9% w/v Sodium Chloride Injection BP
- 5% Dextrose and 0.45% Sodium Chloride Injection
- 5% Dextrose and 0.225% Sodium Chloride Injection
- 10% Dextrose Injection
- Lactated Ringer's Injection USP
- M/6 Sodium Lactate Injection
- Compound Sodium Lactate Injection BP (Hartmann's Solution).

The stability of cefuroxime sodium in 0.9% w/v Sodium Chloride Injection BP and in 5% Dextrose Injection BP is not affected by the presence of hydrocortisone sodium phosphate.

Cefuroxime sodium has also been found compatible when admixed in IV infusion with:

- Heparin (10 and 50 units/mL) in 0.9% w/v Sodium Chloride Injection;
- Potassium Chloride (10 and 40 mEqL) in 0.9% w/v Sodium Chloride Injection BP.

In the absence of other compatibility studies, this medicinal product must not be mixed with other medicinal products apart from those listed as compatible above.

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

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