

Package leaflet: Information for the user

Cefuroxime 750mg & 1.5g Powder for Injection/Infusion Cefuroxime

The name of your medicine is Cefuroxime 750mg & 1.5g Powder for Injection/Infusion, which will be referred to as Cefuroxime Injection throughout this document.

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

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

Cefuroxime injection 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 is used to treat infections of:

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

Cefuroxime Injection is also used:

- to prevent infections during surgery.

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

You must not be given Cefuroxime Injection:

- **if you are allergic (*hypersensitive*) to any cephalosporin** antibiotics or any other ingredients of Cefuroxime Injection (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 if you think that this applies to you. You must not be given Cefuroxime Injection.

Take special care with Cefuroxime Injection

You must look out for certain symptoms such as allergic reactions, skin rashes and gastrointestinal disorders such as diarrhoea while you are being given Cefuroxime Injection. 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.

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.

If you need a blood or urine test

Cefuroxime Injection 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.

Other medicines and Cefuroxime Injection

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 Injection 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.

Contraceptive pills

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

Pregnancy and breast-feeding and fertility

Tell your doctor before you are given Cefuroxime Injection:

- 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 Injection against the risk to your baby.

Driving and using machines

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

Important information about some of the ingredients of Cefuroxime Injection

Cefuroxime Injection 750 mg contains 40.6 mg 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 1.5 g contains 81.3 mg 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 Cefuroxime Injection is given

Cefuroxime Injection 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 usual dose

The correct dose of Cefuroxime Injection 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 100mg Cefuroxime Injection per day divided in two or three doses.

Babies (over 3 weeks) and children

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

Adults and adolescents

750mg to 1.5g of Cefuroxime Injection per day divided into two, three or four doses. Maximum dose: 6g 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 Injection 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

- **fungal infections** on rare occasions, medicines like Cefuroxime Injection 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 for a long time.
- **severe diarrhoea (*pseudomembranous colitis*)**. Medicines like Cefuroxime Injection can cause inflammation of the colon (large intestine), causing severe diarrhoea, usually with blood and mucus, stomach pain and 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 the 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

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 multiforme*.

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 creatine in the blood.

If you get side effects

Tell your doctor or nurse. This includes any possible side effects not listed in this leaflet.

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRAs Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cefuroxime Injection

Your doctor or pharmacist will know how to store Cefuroxime Injection.

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 after 'EXP'. The expiry date refers to the last day of that month. Before it is made up it should be stored below 25°C. Keep the vial in the outer carton in order to protect from light.

After it is made up Cefuroxime Injection should be used immediately but can be stored at 2-8°C (in a refrigerator) for up to 24 hours.

Don't 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 Injection contains

The active substance is cefuroxime (as sodium salt).

Each 750mg vial contains 750mg cefuroxime (as sodium salt).

Each 1.5g vial contains 1.5g cefuroxime (as sodium salt).

There are no other ingredients.

However, see section 2 for further important information about sodium (present as cefuroxime sodium).

What Cefuroxime Injection looks like and contents of the pack

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

Vials contain a white or almost white powder. 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.

Marketing Authorisation Holder

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The following information is intended for medical or healthcare professionals only:

Instructions for reconstitution

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

Addition volumes and solution/suspension concentrations, which may be useful when fractional doses are required				
Vial size	Routes of administration	Amount of water to be added (mL)	Approximate cefuroxime concentration (mg/mL)**	Resulting product
750mg	intramuscular	3mL	216	Suspension
	intravenous bolus	at least 6mL	116	Solution
	intravenous infusion	at least 6mL	116	Solution
1.5g	intramuscular	6mL	216	Suspension
	intravenous bolus	At least 15mL	94	Solution
	intravenous infusion	15mL*	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 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.

Following reconstitution with Water for Injections, chemical and physical in-use stability has been demonstrated for 48 hours at 2-8°C.

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 2-8°C, unless reconstitution/dilution has taken place in controlled and validated aseptic conditions.

Compatibility

1.5g cefuroxime sodium constituted with 15mL Water for Injection may be added to metronidazole injection (500mg/100ml) and both retain their activity for up to 24 hours below 25°C.

1.5g cefuroxime sodium is compatible with azlocillin 1g (in 15ml) or 5g (in 50ml) for up to 24 hours at 4°C or 6 hours below 25°C.

Cefuroxime sodium (5mg/ml) in 5% w/v or 10% w/v xylitol injection may be stored for up to 24 h at 25°C.

Cefuroxime sodium is compatible with aqueous solutions containing up to 1% lidocaine hydrochloride.

Cefuroxime sodium is compatible with the following infusion fluids. It will retain potency for up to 24 hours at room temperature in:

- 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% Sodium Chloride Injection
- 5% Dextrose and 0.45% Sodium Chloride Injection
- 5% Dextrose and 0.225% Sodium Chloride Injection
- 10% Dextrose Injection
- 10% Invert Sugar in Water for Injection
- Ringer's Injection USP
- Lactated Ringer's Injection USP
- M/6 Sodium Lactate Injection
- Compound Sodium Lactate Injection BP (Hartmann's Solution).

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

Cefuroxime sodium has also been found compatible for 24 h at room temperature when admixed in i.v. infusion with:

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

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.

Cefuroxime should not be mixed in the syringe with aminoglycoside antibiotics.

The pH of 2.74% w/v Sodium Bicarbonate Injection BP considerably affects the colour of the solution and therefore this solution is not recommended for the dilution of Cefuroxime. However, if required, for patients receiving Sodium Bicarbonate Injection by infusion Cefuroxime 1.5 g may be introduced into the tube of the giving set.