**PACKAGE LEAFLET: INFORMATION FOR THE PATIENT**

# Cefuroxime 750 mg Powder for Solution for Injection
# Cefuroxime 1.5 g Powder for Solution for Injection or Infusion
**(cefuroxime sodium)**

**Read all of this leaflet carefully before you start using 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.
- 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:**


The name of your medicine is Cefuroxime 750 mg Powder for Injection or Cefuroxime 1.5 g Powder for Injection or Infusion but both will be referred to as Cefuroxime injection throughout this leaflet.

## 1. WHAT CEFUROXIME INJECTION IS AND WHAT IT IS USED FOR

Cefuroxime injection contains cefuroxime, which 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 abdomen
- the skin and soft tissue

Your doctor may also give it to you before an operation to protect you from infection. 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 INJECTION

Your doctor or nurse will make sure it is safe for you to have Cefuroxime injection.

**You must not be given Cefuroxime injection if you:**

- are allergic to cefuroxime or any other cephalosporin antibiotic
- have ever had a severe allergic (hypersensitive) reaction to any other type of betalactam antibiotic (penicillins, monobactams, carbapenems)
- have ever developed a severe skin rash or skin peeling, blistering and /or mouth sores after treatment with cefuroxime or any 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, gastrointestinal disorders such as diarrhoea and fungal infections while you are being given Cefuroxime injection. See ('Conditions you need to look out for') in section 4. You must tell your doctor or nurse if you develop any of these conditions.
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**

This medicine can affect the results of tests for sugar in your urine or blood, and a blood test known as the Coombs test. If you are having tests it is important to tell the doctor and the person taking the sample(s) that you have been given this medicine.

**Other medicines and cefuroxime injection**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

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

- diuretics (water tablets) e.g. furosemide
- aminoglycoside-type antibiotics e.g. gentamicin, neomycin
- probenecid
- oral anticoagulants (to help prevent blood clots) e.g. warfarin

Tell your doctor if this applies to you. You may need extra monitoring while you are being given 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 a condom). Ask your doctor for advice.

**Pregnancy and breast-feeding**
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, tell your doctor before you are given this medicine.

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

**Driving and using machines**
Cefuroxime injection is unlikely to affect your ability to drive or operate machinery but do not drive or use machines if you feel unwell.

**Cefuroxime injection contains sodium** (the main component of cooking/table salt).
Each 750 mg vial contains 41 mg sodium. This is equivalent to 2% of the recommended maximum daily dietary intake of sodium for an adult.
Each 1.5 g vial contains 81 mg sodium. This is equivalent to 4% of the recommended maximum daily dietary intake of sodium for an adult.

## 3. HOW CEFUROXIME INJECTION IS GIVEN

Your doctor will decide which dose you need. Your doctor or nurse will inject the Cefuroxime injection into a muscle or into a vein. In some cases, it may be added to a 'drip' intravenous infusion.

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

***Adults and adolescents*** are usually given 750 mg to 1.5 g of cefuroxime two, three or four times daily. The maximum dose is 6 g per day. If you have kidney trouble, you may be given a lower dose.

Your doctor may give you 1.5 g of Cefuroxime injection before surgery to protect you from infection. You may receive further doses of 750 mg of Cefuroxime injection after the operation.

***Babies (over 3 weeks) and children*** will usually be given 30 to 100 mg for each kilogram of their body weight each day. This will be divided into three or four doses.

***Newborn babies*** **(0-3 weeks)** will usually be given 30 to 100 mg for each kilogram of their body weight each day. This will be divided into two or three doses.

**If you are given more Cefuroxime injection than you expect**
It is most unlikely that you will be given too much medicine by the nurse or doctor. Your doctor and nurse will be monitoring your progress, and checking the medicine that you are given. However, always ask if you are not sure why you are getting a dose of medicine.

**If you think you have missed a dose of Cefuroxime injection**
Your doctor or nurse have instructions when to give you your medicine. It is unlikely that you will not be given the medicine as it has been prescribed. However, if you think you may have missed a dose, talk to your nurse or doctor. It is important that the course of treatment your doctor has prescribed is given. You may start to feel better but it is important not to stop this medicine until the doctor advises, otherwise your condition may get worse again.

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.

**Conditions you need to look out for**

Some people given cefuroxime may get an allergic reaction or potentially serious skin reaction. Tell a doctor or nurse **immediately** if you get any of the following symptoms:

- severe allergic reaction. Signs include feeling lightheaded or faint, sudden wheezing, chest tightness or breathing difficulties, a fast heartbeat, feeling sick, clammy skin, confusion and anxiety, swelling particularly of the face or mouth, a raised and itchy rash.
- skin rash, which may blister, and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge).
- widespread rash with blisters and peeling skin
- 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 being given cefuroxime include:

- fungal infections - medicines like cefuroxime can cause an overgrowth of yeast (*Candida*) in the body which can lead to fungal infections such as thrush; this 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.

Tell your doctor or nurse if you get any of these symptoms.

**Other side effects**

***Common*** (may affect up to 1 in 10 people):
- pain at the site of injection, swelling and redness along a vein

Common side effects that may show up in blood tests:
- increases in the levels of enzymes produced by the liver
- changes in the white blood cell count
- decrease in blood haemoglobin concentration

***Uncommon*** (may affect up to 1 in 100 people):
- diarrhoea, nausea, stomach pain
- skin rash, itchy, bumpy rash (hives)

Uncommon side effects that may show up in blood tests:
- low levels of white blood cells
- increase in bilirubin (a substance produced by the liver)
- positive Coombs test.

***Not known*** (frequency cannot be estimated from the available data):
The following side effects have occurred but their exact frequency is unknown:
- high temperature (fever)
- inflammation in the kidney and blood vessels
- easy bruising

Side effects that may show up in blood tests:
- decreases in the very tiny blood cells called platelets (cells that help blood to clot), resulting in bruising and prolonged bleeding
- low levels of red blood cells
- increase in blood levels of urea nitrogen and serum creatinine

**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 INJECTION

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

The un-opened dry powder should be stored below 30ºC, in the original package.
The doctor, pharmacist or nurse will make up your medicine. From a microbiological point of view, the reconstituted solution should be used immediately. If not used immediately, the reconstituted solution should be stored at 2-8ºC for no longer than 24 hours.

This medicine must not be used 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 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 to protect the environment.

## 6. CONTENTS OF THE PACK AND OTHER INFORMATION

**What Cefuroxime injection contains**
The active substance is cefuroxime sodium. There are no other ingredients.

**What Cefuroxime injection looks like and contents of the pack**
Cefuroxime 750 mg powder for injection is a white or off-white powder which forms:

- an off-white, opaque suspension for intramuscular use when reconstituted with 3 ml of Water for Injections.
- a yellowish, clear solution for intravenous use when reconstituted with 6 ml of Water for Injections.

Cefuroxime 1.5 g powder for injection or infusion is a white or off-white powder which forms:

- a yellowish, clear solution for intravenous injection when reconstituted with 15 ml of Water for Injections.
- a yellowish, clear solution for intravenous infusion when reconstituted with 50 ml of Water for Injections.

Cefuroxime 750 mg powder for injection is available in 10 ml vials in packs of 1, 5, 10 or 100 vials.

Cefuroxime 1.5 g powder for injection or infusion is available in 20 and 100 ml vials in packs of 1, 10 or 20 vials.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

**Marketing Authorisation Holder:**
Reig Jofre UK Limited
Unit 9A Caddsdown Business Support Centre, Caddsdown Industrial Park,

Bideford, Devon, EX39 3DX, UK

**Manufacturer:**
Laboratorio Reig Jofre, S.A.
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**PACKAGE LEAFLET: INFORMATION FOR THE HEALTHCARE PROFESSIONAL**

# Cefuroxime 750 mg Powder for Solution for Injection
# Cefuroxime 1.5 g Powder for Solution for Injection or Infusion
**(cefuroxime sodium)**

## Instructions for reconstitution

On reconstitution, product must be mixed gently for at least 90 seconds prior to withdrawing into the syringe; and if not given immediately, again just prior to administration.

### Cefuroxime 750 mg Powder for Solution for Injection

When dissolved in Water for Injections Cefuroxime 750 mg forms an off-white, opaque suspension for intramuscular use or a yellowish, clear solution for intravenous administration.

Intramuscular injection

750 mg of cefuroxime should be dissolved in 3 ml of Water for Injections. Shake gently to produce an opaque suspension.

Intravenous injection

750 mg of cefuroxime should be dissolved in 6 ml of Water for Injections. Shake gently to produce a clear solution. This solution may be given directly into the vein or introduced into the tubing of the giving set if the patient is receiving parenteral fluids.

### Cefuroxime 1.5 g Powder for Solution for Injection or Infusion

When dissolved in Water for Injections Cefuroxime 1.5 g forms an off-white, opaque suspension for intramuscular use or a yellowish, clear solution for intravenous administration.

Intramuscular injection

1.5 g of cefuroxime should be dissolved in 6 ml of Water for Injections. Shake gently to produce an opaque suspension. Not more than 750 mg cefuroxime should be injected at one site.

Intravenous injection

1.5 g of cefuroxime should be dissolved in 15 ml of Water for Injections. Shake gently to produce a clear solution. This solution may be given directly into the vein or introduced into the tubing of the giving set if the patient is receiving parenteral fluids.

Intravenous infusion

*20 ml vial:* 1.5 g of cefuroxime should be dissolved in 15 ml of Water for Injections. Shake gently to produce a clear solution. The reconstituted solution should then be added to 50 or 100 ml of compatible infusion fluid (see information on compatibility, below).

*100 ml vial*: 1.5 g of cefuroxime should be dissolved in 50 ml of Water for Injections. Shake gently to produce a clear solution.

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

When Water for Injections is added to cefuroxime the resulting volume is affected by the displacement factor of the drug substance, giving the approximate concentrations in mg/ml detailed in the table below.

| Addition volumes and concentrations, which may be useful when fractional doses are required | | | | |
|---|---|---|---|---|
| Vial size | Route of administration | Physical State | Amount of water to be added (ml) | Approximate cefuroxime concentration (mg/ml) |
| **750 mg powder for solution for injection** | | | | |
| 750 mg | intramuscular<br>intravenous bolus | suspension<br>solution | 3 ml<br>6 ml | 216<br>116 |
| **1.5 g powder for solution for injection or infusion** | | | | |
| 1.5 g | intramuscular<br>intravenous bolus<br>intravenous infusion | suspension<br>solution<br>solution | 6 ml<br>15 ml<br>15 ml* | 216<br>94<br>94 |

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

**Compatibility**

**Cefuroxime 750 mg Powder for Solution for Injection and Cefuroxime 1.5 g Powder for Solution for Injection or Infusion**

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

**Cefuroxime 1.5 g Powder for Solution for Injection or Infusion**

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

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

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

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% 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
- 10% Invert Sugar in Water for Injections
- 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 0.9% w/v Sodium Chloride Injection BP and in 5% Dextrose Injection is not affected by the presence of hydrocortisone sodium phosphate.

Cefuroxime sodium has also been found compatible for 24 hours at room temperature when admixed in IV infusion with:

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

**Marketing authorisation numbers**
Cefuroxime 750 mg Powder for Solution for Injection: PL 44095/0032
Cefuroxime 1.5 g Powder for Solution for Injection or Infusion: PL 44095/0033

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