**Package Leaflet: Information for the user**
Cefuroxime 1500 mg powder for solution for injection/infusion
Cefuroxime

**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 or pharmacist.
- 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

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 use Cefuroxime

**You must not be given Cefuroxime:**
- **if you are allergic** to **any cephalosporin antibiotics** or any of the other ingredients of Cefuroxime (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).

→ **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**

Talk to your doctor, pharmacist or nurse before using Cefuroxime. 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 .

**Pregnancy and 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.**

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This medicine contains 81.26 mg of sodium (main component of cooking salt) is each vial. This is equivalent to 4.1 % of the recommended maximum daily dietary intake of sodium for an adult.

## 3. How to use Cefuroxime

**Cefuroxime is usually to be 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 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*).

**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, pharmacist 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.

**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 or nurse. This includes any possible side effects not listed in this leaflet. By reporting side affects you can help provide more information on the safety of this medicine.
For UK – You can also report side effects directly via the Yellow Card Scheme at:
www.mhra.gov.uk/yellowcard
For Ireland – via HPRA Pharmacovigilance, Earlsfort Terrace, IRL-Dublin 2: Tel +353 1 6764971; Fax +353 1 676 2517. Website: www.hpra.ie; Email: medsafety@hpra.ie

## 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 which is stated on the pack after EXP. The expiry date refers to the last day of that month.

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

Once Cefuroxime powder is made up into a suspension/solution for injection, it should be used immediately. If not used immediately, the ready-to-use solution/suspension should be stored in the refrigerator (between 2 – 8 °C) and used within 5 hours.

Do not use Cefuroxime if you notice visible signs of deterioration such as particulate matter and discoloration. Any unused solution/suspension should be thrown away.

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 (1500 mg) as cefuroxime sodium.

**What Cefuroxime looks like and contents of the pack:**
Cefuroxime powder is normally mixed with water for injection to make up a clear solution for injection or infusion into veins (intravenous) or to make up a suspension for injection into muscles (intramuscular). Once made up, your doctor may mix the Cefuroxime solution with other suitable fluids for infusion. Solutions and suspensions can range in colour from clear to yellow coloured depending on concentration, diluent and storage conditions used.
Cefuroxime 1500 mg powder for suspension for injection or solution for injection/infusion comes in packs containing 1 and 10 glass vials of powder, closed with rubber stoppers, aluminium caps and red plastic flip-off caps together.

Not all the pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer:**
Marketing Authorisation Holder:
For UK
Fresenius Kabi Limited
Cestrian Court, Eastgate Way,
Manor Park, Runcorn, Cheshire, WA7 1NT, UK

For IRL
Fresenius Kabi Deutschland GmbH
Else-Kroener Strasse 1
Bad Homburg v.d.H 61352,
Germany

**Manufacturer:**
Labesfal – Laboratorios Almiros SA
Lagedo, 3465-157 Santiago Besteiros, Portugal.

**This medicinal product is authorised in the Member States of the EEA under the following names:**

| Name of the Member State | Name of the medicinal product |
|---|---|
| Belgium | Cefuroxim Fresenius Kabi 1500 mg poeder voor oplossing voor injectie of infusie, poudre pour solution injectable ou pour perfusion, Pulver zur Herstellung einer Injektionslösung/ Infusionslösung |

| | |
|---|---|
| Czech Republic | Cefuroxim Kabi 1500 mg |
| Denmark | Cefuroxim Fresenius Kabi 1,5 g |
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| Greece | Cefuroxime Kabi κόνις για παρασκευή διαλύματος για ένεση/έγχυση,, 1500mg |
| Hungary | Cefuroxim Kabi 1500 mg por oldatos injekcióhoz vagy infúzióhoz |
| Ireland | Cefuroxime 1.5 g, powder for solution for injection/infusion |
| Netherlands | Cefuroxim Fresenius Kabi 1500 mg, poeder voor oplossing voor injectie/infusie |
| Norway | Cefuroxim Fresenius Kabi |
| Poland | Cefuroxim Kabi |
| Sweden | Cefuroxim Fresenius Kabi 1500 mg pulver till injektions-/infusionsvätska, lösning |
| Slovak Republic | Cefuroxim Kabi 1500 mg |
| United Kingdom | Cefuroxime 1.5 g powder for solution for injection/infusion |

**This leaflet was last revised in 09/2020.**

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The following information is intended for healthcare professionals only:

**Instructions for reconstitution**

Addition 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 | Amount of water to be added (ml) | Approximate cefuroxime concentration (mg/mL)** | | Resulting product |
| 1.5 g | intramuscular<br>intravenous bolus<br>intravenous infusion | 6 mL<br>at least 15mL<br>15 mL* | 216<br>94<br>94 | Suspension<br>Solution<br>Solution |

**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/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.

Preparation of solution for intravenous infusion
Cefuroxime 1500 mg should be reconstituted following the instructions for reconstitution of intravenous injection with water for injection (see table above).
Further dilution should take place in 50-100 ml of one of the following compatible infusion fluids prior to intravenous infusion administration:

Cefuroxime sodium is compatible with the following infusion fluids. It will remain potency for up to 5 hours at 2°C to 8°C in:
- water for injections
- 0.9 % sodium chloride solution
- 5 % glucose solution.

Intravenous Cefuroxime injection should be given over 3 – 5 minutes.
Intravenous Cefuroxime infusion should be given over 30 to 60 minutes.

For singly use only

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

After reconstitution, chemical and physical in-use stability has been demonstrated for 5 hours at 2ºC to 8ºC.

From a microbiological point of view, the product should be used immediately.
If not used immediately, in-use storage times and conditions are the responsibility of the user.

Special precautions for storage
Do not store above 25ºC
Keep the vials in outer carton in order to protect from light.