

PACKAGE LEAFLET: INFORMATION FOR THE USER
Cefuroxime 250 mg powder for solution for injection
Cefuroxime 750 mg powder for solution for injection
Cefuroxime 1500 mg powder for solution for injection or 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 nurse.
- If you get any of the 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 the 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 Stravencon 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**
- 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.

Take special care with 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 Stravencon contains sodium

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

Cefuroxime strength	Amount per vial
250 mg	13.8 mg
750 mg	41.4 mg
1500 mg	80.5 mg

3. HOW CEFUROXIME IS GIVEN

Cefuroxime is usually 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.

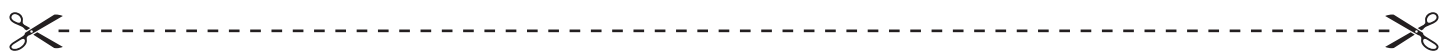
Adults and adolescents

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.



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

Instructions for reconstitution

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

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)**
250 mg powder for solution for injection				
250mg	intramuscular	suspension	1 mL	216
	intravenous bolus	solution	At least 2 mL	116
750 mg powder for solution for injection				
750mg	intramuscular	suspension	3 mL	216
	intravenous bolus	solution	At least 6 mL	116
1500 mg powder for solution for injection or infusion				
1500 mg	intramuscular	suspension	6 mL	216
	intravenous bolus	solution	At least 15mL	94
	intravenous infusion	solution	15 mL*	94

* Reconstituted solution to be added to 50 or 100mL 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.*

4. POSSIBLE SIDE-EFFECTS

Like all medicines, Cefuroxime 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 Stravencon 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 including 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.

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 creatinine in the blood.

Reporting of side effects

You can help make sure medicines remain as safe as possible by reporting any unwanted side-effects as follows:

HPRa Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: 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 shown on the pack 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. Once the powder has been mixed, your doctor or nurse will ensure that it is stored correctly.

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 protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Cefuroxime contains

One vial contains 250 mg, 750 mg or 1500 mg of cefuroxime as cefuroxime sodium. The product contains no other ingredients.

What Cefuroxime Stravencon looks like and the contents of the pack

Powder for solution for injection (250 mg, 750 mg).

Powder for solution for injection or infusion (1500 mg).

Cefuroxime Stravencon is a white or almost white powder.

Pack sizes:

10 x 250 mg, 10 x 750 mg and 10 x 1500 mg

1 x 250 mg, 1 x 750 mg and 1 x 1500 mg

Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Stravencon Ltd.
Landmark House
17 Hanover Square
Mayfair
London W1S 1HU
UK

Manufacturer:

IPG Pharma Ltd.
Atrium Court
The Ring
Bracknell
Berkshire
RG12 1BW
UK

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Compatibility

Cefuroxime sodium (5 mg/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:

Sodium Chloride Injection BP 0.9% w/v
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 mEq/L) in 0.9% Sodium Chloride Injection.