Package leaflet: Information for the patient

Cefuroximnatrium Sandoz injectie 250 mg, poeder voor oplossing voor injectie
Cefuroximnatrium Sandoz injectie 750 mg, poeder voor oplossing voor injectie
Cefuroximnatrium Sandoz injectie 1500 mg, poeder voor oplossing voor injectie

cefuroxime (as 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 or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1 What [Nationally completed name] is and what it is used for

[Nationally completed name] 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.
[Nationally completed name] is used to treat infections of:
- the lungs or chest
- the urinary tract
- the skin and soft tissue
- the abdomen

[Nationally completed name] is also used:
• to prevent infections during surgery.

2 What you need to know before you are given [Nationally completed name]

You must not be given [Nationally completed name]:
- **if you are allergic to cefuroxime** to **any cephalosporin antibiotics** or any of the other ingredients of this medicine 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 [Nationally completed name] if you think that this applies to you. You must not be given [Nationally completed name].

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using [Nationally completed name].
You must look out for certain symptoms such as allergic reactions and gastrointestinal disorders such as diarrhoea while you are being given [Nationally completed name]. 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 [Nationally completed name].

Take special care with [Nationally completed name]

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
[Nationally completed name] 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 [Nationally completed name].

Other medicines and [Nationally completed name]
Tell your doctor if you are taking, have recently taken or might take any other medicine.
This includes medicines you can obtain without a prescription.
Some medicines may affect how [Nationally completed name] 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 [Nationally completed name].

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 or pharmacist for advice before taking this medicine.
Your doctor will consider the benefit of treating you with [Nationally completed name] against the risk to your baby.

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

[Nationally completed name] contains sodium
[Nationally completed name] contains 2.09 mmol (equivalent to 48 mg) of sodium per gram. This should be taken into consideration by patients on a sodium controlled diet.

[Nationally completed name] strength	Amount of sodium per vial
250 mg	13 mg This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium-free'.
750 mg	39 mg This medicine contains 39 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 1,95 % of the recommended maximum daily dietary intake of sodium for an adult.
1500 mg	77 mg This medicine contains 77 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 3,85 % of the recommended maximum daily dietary intake of sodium for an adult.

3 How [Nationally completed name] is given

[Nationally completed name] 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 recommended dose is:
The correct dose of [Nationally completed name] 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 [Nationally completed name] 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 [Nationally completed name] per day divided in three or four doses.

Adults and adolescents
750 mg to 1.5 g of [Nationally completed name] two, three or four times daily.

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.

Stop using cefuroxime and seek medical attention immediately if you notice any of the following symptoms:
- reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis).
- a red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalised exanthematous pustulosis).

Conditions you need to look out for
A small number of people taking [Nationally completed name] 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**.
- **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 conditions you need to look out for while taking [Nationally completed name] **include:**
- **fungal infections** on rare occasions, medicines like [Nationally completed name] 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 [Nationally completed name] for a long time.
- **severe diarrhoea (*Pseudomembranous colitis*).** Medicines like [Nationally completed name] 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 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 in the blood 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 national reporting system listed in Appendix V*. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Nationally completed name]

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 carton/ bottle after "EXP".

The expiry date refers to the last day of that month.

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

For storage conditions of the reconstituted/diluted medicinal product, see at the end of the package leaflet 'The following information is intended for medical or healthcare professionals only'.

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 protect the environment.

6. Contents of the pack and other information

What [Nationally completed name] contains
- The active substance is cefuroxime

Each vial contains 250 mg of cefuroxime (as cefuroxime sodium)
Each vial contains 750 mg of cefuroxime (as cefuroxime sodium)
Each vial contains 1500 mg of cefuroxime (as cefuroxime sodium)
Each infusion bottle contains 1500 mg of cefuroxime (as cefuroxime sodium)

What [Nationally completed name] looks like and contents of the pack

[Nationally completed name] 250 mg, powder for solution/suspension for injection white to yellowish powder.
15 ml vials of clear glass type III (Ph. Eur.) closed with rubber stopper and flip-off bordered caps.
[Nationally completed name] 750 mg, powder for solution/suspension for injection white to yellowish powder.
15 ml vials of clear glass type III (Ph. Eur.) closed with rubber stopper and flip-off bordered caps.
[Nationally completed name] 1500 mg, powder for solution for injection white to yellowish powder.
30 ml vials of clear glass type III (Ph. Eur.) closed with rubber stopper and flip-off bordered caps.
[Nationally completed name] 1500 mg, powder for solution for infusion white to yellowish powder.
100 ml infusion bottles of clear glass type II (Ph. Eur.) closed with rubber stopper and flipp-off bordered caps.

Vials:
250 mg: 1, 5, 10, 25, 50, 100 vials
750 mg: 1, 5, 10, 25, 50, 100 vials
1500 mg: 1, 5, 10, 25, 50, 100 vials

Bottle:
1500 mg: 1, 5, 10, 25, 50, 100 infusion bottles.

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant

Vergunninghouder
Sandoz B.V., Hospitaaldreef 29, 1315 RC Almere, Nederland

Fabrikant
Sandoz GmbH
Biochemiestrasse 10
6250 Kundl
Oostenrijk

In het register ingeschreven onder:
Cefuroximnatrium Sandoz injectie 250 mg, poeder voor oplossing voor injectie - RVG 28712
Cefuroximnatrium Sandoz injectie 750 mg, poeder voor oplossing voor injectie - RVG 28713
Cefuroximnatrium Sandoz injectie 1500 mg, poeder voor oplossing voor injectie - RVG 28714

Dit medicijn is geregistreerd in lidstaten van de Europese Economische Ruimte en in het Verenigd Koninkrijk (Noord-Ierland) onder de volgende namen:
Nederland: Cefuroximnatrium sandoz injectie 250, 750, 1500 mg, poeder voor oplossing voor injectie
Oostenrijk: Cefuroxim Sandoz 750 mg –Pulver zur Herstellung einer Injektionslösung/-suspension
Verenigd Koninkrijk: Cefuroxim 750, 1500 mg powder for solution/suspension for injection

Deze bijsluiter is voor het laatst goedgekeurd in februari 2024.

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

[Nationally completed name] 250 mg / 750 mg / 1500 mg powder for solution for injection or infusion
cefuroxime

This is an extract from the Summary of Product Characteristics to assist in the administration of [Nationally completed name]. When determining appropriateness of use in a particular patient, the prescriber should be familiar with the SPC.

For slow intravenous injection/infusion and intramuscular injection.

INCOMPATIBILITIES WITH DILUENTS AND OTHER MEDICINAL PRODUCTS
- [Nationally completed name] should not be added with other antibiotics, in the same syringe or solution for infusion. This concerns expecially aminoglycosides.
- [Nationally completed name] should not be mixed with solutions containing sodium bicarbonate.

INSTRUCTIONS FOR USE, HANDLING AND DISPOSAL
Aseptic techniques should be used to reconstitute the solution. The reconstituted solution is stable for 2 hours at room temperature and 24 h at 2 °C – 8 °C.

[Nationally completed name] is compatible with several commonly used intravenous infusion fluids:

- water for injection
- 0.9 % sodium chloride solution
- 5 % glucose solution

The compatibility of [Nationally completed name] in other infusion fluids should be checked before use.

When reconstituted for intramuscular or intravenous injection, the white to yellowish powder gives a colourless to slightly yellow suspension and a colourless to brownish solution respectively. Do not use if any particulate matter is visible. Withdraw only one dose.
Any unused solution should be discarded.

Method of administration:
In order to prevent any risk of infection, the preparation of the infusion should be done in close aseptic conditions. Do not delay the infusion after the preparation of the solution.

Intramuscular injection

[Nationally completed name] *250 mg / 750 mg powder for solution/suspension for injection:* Add 1 ml of water for injections or 1.0 % lidocain solution respectively to [Nationally completed name] *250 mg*] and 3 ml to [Nationally completed name] *750 mg*. Shake gently to produce a homogenous suspension. [Nationally completed name] *1500 mg*, powder for solution for injection, should not be administered intramuscularly.

Intravenous injection

[Nationally completed name] 250 mg / 750 mg / 1500 mg powder for solution/suspension for injection:
Dissolve [Nationally completed name] *250 mg* in at least 2 ml of water for injections, 0.9 % sodium chloride solution or 5 % glucose solution, [Nationally completed name *750 mg* in at least 6 ml and [Nationally complete name] *1500 mg* in 15 ml.
Shake gently to produce a clear solution.

Short intravenous infusion (e.g. up to 30 minutes)

[Nationally completed name] *1500 mg powder for solution/suspension for infusion*:
[Nationally completed name] *1500 mg* may be dissolved in 50 ml water for injection, 0.9 % sodium chloride solution or 5 % glucose solution. These solutions may be given directly into the vein or introduced into the tubing of the giving set.
Shake gently to produce a clear solution.

The contents and concentrations of cefuroxime as solution/suspension are shown in the table below

mg cefuroxime per vial	addition of ml solvent	volume ml of final solution/suspension	Concentration mg/ml
250	2	2.2	114
750	6	6.8	110
1500	15	16.5	91
1500	50	51.5	29