Package leaflet: Information for the user

Cefuroxime 750 mg powder for solution for injection/infusion
Cefuroxime 1500 mg powder for solution for injection/infusion

cefuroxime

Read all of this leaflet carefully before you are given 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 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 bronchi
- 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 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 beta-lactam 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.
- if you are allergic to lidocaine and you are to be given cefuroxime reconstituted in lidocaine solution as an injection into a muscle.

Tell your doctor before cefuroxime is given to you if you think that this applies to you. You must not be given cefuroxime.

Warnings and precautions
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 this medicine. 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.

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 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 or nurse, if you are using, have recently used or might use any other medicines.

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 given this medicine.

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

Pregnancy and 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 for advice before taking this medicine.
Your doctor will consider the benefit of treating you with cefuroxime against the risk to your baby.

Driving and using machines
This medicine is unlikely to have an effect on the ability to drive and use machines. However, do not drive or use machines if you do not feel well.

Cefuroxime contains sodium
Cefuroxime 750 mg powder for solution for injection/infusion
This medicine 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 1500 mg powder for solution for injection/infusion
This medicine contains 81.3 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 4.1 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How Cefuroxime is given

Cefuroxime 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 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 1500 mg 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.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

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

For single use only.

Method of administration

Cefuroxime should be administered by intravenous injection over a period of 3 to 5 minutes directly into a vein or via a drip tube or infusion over 30 to 60 minutes, or by deep intramuscular injection.

Intramuscular injections should be injected well within the bulk of a relatively large muscle and not more than 750 mg should be injected at one site.
Caution is required when 1500 mg as a unit dose is administered by intramuscular injection: 2 doses of 750 mg should be injected, each one in a separate site.
For doses greater than 1500 mg intravenous administration should be used.

If the solvent used for reconstitution of cefuroxime for intramuscular injection is lidocaine, the reconstituted medicinal product should never be administered intravenously. The information in the Summary of Product Characteristics of lidocaine should be considered.

Instructions for reconstitution

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

	Additional volumes and concentrations, which may be useful when fractional doses are required			
Vial size	Routes of administration	Physical state	Amount of water for injections to be added (ml)	Approximate cefuroxime concentration (mg/ml)**
750 mg	intramuscular intravenous bolus intravenous infusion	suspension solution solution	3 ml at least 6 ml at least 6 ml*	234 122 122
1500 mg	intravenous bolus intravenous infusion intramuscular could also be given if necessary ***	solution solution suspension	at least 15 ml 15 ml* 6 ml	99 99 238

** Reconstituted solution to be added to 50 or 100 ml of compatible infusion solution (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.*
**** The method of preparation of both doses of 750 mg to be administered at a same period of time should be in accordance with standard quality requirements (see "Method of administration" above).*

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 (frequency not known)
A small number of people receiving 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) (These may be signs of erythema multiforme).
- **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 you are given cefuroxime include (frequency not known):
- **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 are given 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 or nurse immediately if you get any of these symptoms.

Other side effects

Common side effects (may affect up to 1 in 10 patients)
- injection site pain, swelling and redness along a vein

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

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

Not known (cannot be estimated from the available data)
- high temperature (fever)
- allergic reactions
- inflammation in the kidney and blood vessels
- red blood cells destroyed too quickly (haemolytic anaemia)

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. You can also report side effects directly via Yellow Card Scheme, Website: 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

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 and carton after EXP. The expiry date refers to the last day of that month.

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

Intravenous or intramuscular injection

Shelf life after reconstitution in vial:
Chemical and physical in-use stability has been demonstrated for 6 hours at 25 °C and 72 hours at 2 to 8 °C, when reconstituted with water for injection (see "The following information is intended for healthcare professionals only" below).

From a microbiological point of view, the reconstituted 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 to 8 °C, unless reconstitution has taken place in controlled and validated aseptic conditions.

Intravenous infusion

The reconstituted solution should be diluted immediately after reconstitution.

Shelf life after reconstitution and dilution:
Chemical and physical in-use stability of the diluted reconstituted solution has been demonstrated for 6 hours at 25 °C and 72 hours at 2 to 8 °C, when using one of the compatible solvents for further dilution (see "The following information is intended for healthcare professionals only" below).

From a microbiological point of view, the diluted 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 to 8 °C, unless reconstitution/dilution has taken place in controlled and validated aseptic conditions.

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 Cefuroxime contains
– The active substance is cefuroxime.

Cefuroxime 750 mg powder for solution for injection/infusion
Each vial contains 750 mg of cefuroxime (as cefuroxime sodium).

Cefuroxime 1500 mg powder for solution for injection/infusion
Each vial contains 1500 mg of cefuroxime (as cefuroxime sodium).

What Cefuroxime looks like and contents of the pack
Cefuroxime is white or almost white powder for solution for injection/infusion filled in colourless glass vial with rubber stopper sealed with aluminium seal and blue (750 mg)/orange (1500 mg) plastic flip-off cap.

The vials are placed into outer cartons.

Pack sizes: 1 or 10 vials.

Not all pack sizes may be marketed.

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Compatibility
1500 mg cefuroxime sodium constituted with 15 ml water for injection may be added to metronidazole injection (500 mg/100 ml).
1500 mg cefuroxime sodium is compatible with azlocillin 1 g (in 15 ml) or 5 g (in 50 ml).
Cefuroxime sodium (5 mg/ml) in 5 % or 10 % xylitol injection may be used.
Cefuroxime sodium is compatible with aqueous solutions containing up to 1 % lidocaine hydrochloride (for intramuscular injection only). Lidocaine should never be administered intravenously.

Cefuroxime sodium is compatible with the following infusion fluids:
- 9 mg/ml (0.9 %) sodium chloride solution
- 50 mg/ml (5 %) glucose solution
- 40 mg/ml (4 %) glucose solution and 1.8 mg/ml (0.18 %) sodium chloride solution
- 50 mg/ml (5 %) glucose solution and 9 mg/ml (0.9 %) sodium chloride solution
- 50 mg/ml (5 %) glucose solution and 4.5 mg/ml (0.45 %) sodium chloride solution
- 50 mg/ml (5 %) glucose solution and 2.25 mg/ml (0.225 %) sodium chloride solution
- 100 mg/ml (10 %) glucose solution
- lactated Ringer's solution (Hartmann's solution)

The stability of cefuroxime sodium in 9 mg/ml (0.9 %) sodium chloride solution and in 50 mg/ml (5 %) glucose solution is not affected by the presence of hydrocortisone sodium phosphate.

Cefuroxime sodium has also been found compatible when admixed in IV infusion with:
- heparin (10 and 50 units/ml) in 9 mg/ml (0.9 %) sodium chloride solution for infusion
- potassium chloride (10 and 40 mEq/l) in 9 mg/ml (0.9 %) sodium chloride solution for infusion

After addition of the specified amount of diluent for intramuscular injection, a suspension is formed. The colour of suspension is almost white to yellowish-white.

After addition of the specified amount of diluent for intravenous injection or infusion, a clear yellowish solution is formed. The intensity of colour of the solution after reconstitution/dilution may vary, depending on the duration of storage and concentration, but this does not affect the efficacy of the medicinal product. The solution should be visually inspected prior to use. Only clear, yellowish solutions free from particles should be used.

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