Package leaflet: Information for the user

Cefuroxime 750mg & 1.5g powder for solution for injection or infusion
cefuroxime sodium

Read all of this leaflet carefully before you start taking 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 pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Cefuroxime Injection is and what it is used for

Cefuroxime Injection 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 skin and soft tissue
- the abdomen

Cefuroxime Injection 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 Injection during your treatment.

2. What you need to know before you are given Cefuroxime Injection

You must not be given Cefuroxime Injection
- if you are allergic to any cephalosporin antibiotics or any of the other ingredients of Cefuroxime Injection (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 Cefuroxime Injection if you think that this applies to you. You must not be given Cefuroxime Injection

Take special care with 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.

Warnings and precautions
Talk to your doctor or pharmacist before you are given Cefuroxime Injection.

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 Injection. 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 Injection.

If you need a blood or urine test
Cefuroxime Injection 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 Injection.

Other medicines and Cefuroxime Injection
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines you can obtain without a prescription.
Some medicines may affect how Cefuroxime Injection 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 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, 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 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 should not affect your ability to drive or use machines.

Cefuroxime Injection 750mg contains 40.6mg 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 Injection 1.5 g contains 81.3mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 4% of the recommended maximum daily dietary intake of sodium for an adult.

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

3. How you are given Cefuroxime Injection

Cefuroxime Injection 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 recommended dose
The correct dose of Cefuroxime Injection 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 and how well your kidneys are working.

Use in adults and adolescents:
750mg to 1.5g of Cefuroxime Injection two, three or four times daily. Maximum dose: 6g per day.

Use in babies (over 3 weeks) and children:
For every 1kg the baby or child weighs, they'll be given 30 to 100mg of Cefuroxime Injection per day divided in three or four doses.

Use in newborn babies (0 -3 weeks):
For every 1kg the baby weighs, they'll be given 30 to 100mg Cefuroxime Injection per day divided in two or three doses.

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 are given more Cefuroxime Injection than you should receive
It is unlikely that you will be given too much, but if you think that you have been given too much Cefuroxime Injection, tell your doctor, pharmacist or nurse immediately. Signs might include fits (convulsions).
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them. All medicines can cause allergic reactions, although serious allergic reaction are very rare.

Contact a doctor or nurse immediately if you get any of these symptoms:
- High temperature (fever), a sore throat or other signs of an infection. **Common (may affect up to 1 in 10 people)**
- Abnormal reduction in white blood cells (leucopenia) – shown by blood tests. **Uncommon (may affect up to 1 in 100 people)**
- Get potentially serious allergic reactions. 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).
- **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*). **Not known (cannot be estimated from available data)**
- **fungal infections** on rare occasions, medicines like Cefuroxime Injection 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 Injection for a long time. **Not known (cannot be estimated from available data)**
- **severe diarrhoea (*Pseudomembranous colitis*).** Medicines like Cefuroxime Injection can cause inflammation of the colon (large intestine), causing severe diarrhoea, usually with blood and mucus, stomach pain, fever. **Not known (cannot be estimated from available data)**

- Decrease in the number of platelets in the blood resulting in bruising easily or episodes of excessive bleeding (Thrombocytopenia and haemolytic anaemia). **Not known (cannot be estimated from available data)**
- Changes in kidney function shown by blood or urine tests. **Not known (cannot be estimated from available data)**

Other side effects have also been reported:
Common (may affect up to 1 in 10 people)
- Temporary pain at the injection site
- Temporary changes in your blood such as reduced red blood cells and reduced haemoglobin levels or changes in liver function, which will be shown by blood tests

Uncommon (may affect up to 1 in 100 people)
- Rash
- Itchy red wheals (urticaria)
- Diarrhoea and nausea (feeling sick)
- Temporary yellowing of the skin and whites of the eyes which usually return to normal after treatment (due to an increase in a substance made in the liver called bilirubin)
- Positive Coombes test (blood test)

Not known (cannot be estimated from available data)
- High temperature and chills (fever)
- Encephalopathy (non-inflammatory brain disease)
- Convulsions
- Myoclonus (muscle-twitching)

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 the 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 Injection

Cefuroxime Injection is for use in hospital only and the expiry date and storage instructions stated on the vial label and carton are for the doctor, nurse or pharmacist's information. The doctor, pharmacist or nurse will make up your medicine.
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.. The expiry date refers to the last day of that month.
Before it is made up it should be stored below 25ºC.
Keep the vial in the outer carton in order to protect from light.
For single use only. Discard any unused contents.
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 Injection contains

The active substance is cefuroxime (as sodium salt)
Each 750mg vial contains 750mg cefuroxime (as sodium salt). Each 1.5g vial contains 1.5g cefuroxime (as sodium salt).
There are no other ingredients.
However, see section 2 for further important information about sodium (present as cefuroxime sodium).

What Cefuroxime Injection looks like and contents of the pack
Cefuroxime Injection is contained in glass vials with rubber stoppers. Pack sizes of 5, 10, 50 or 100 vials for Cefuroxime 750mg Powder for Injection and 1, 10 or 50 vials for Cefuroxime 1.5g Powder for Injection.
Vials contain an off-white to slightly yellow powder which will be made up with Water for Injections or other recommeneded diluting solution. When made up for injection into a muscle, it becomes off-white and opaque. When made up for injection into a vein, it may be yellowish.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Flynn Pharma Ltd
5th Floor,
40 Mespil Road,
Dublin 4,
IRELAND, D04 C2N4

Manufacturer

ACS DOBFAR S.P.A.
Via A. Fleming, 2
37135 Verona
Italy

Or

ACS DOBFAR S.P.A
Nucleo Industriale S. Atto
S. Nicolo a Tordino
64100 Teramo
Italy
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The following information is intended for healthcare professionals only:

Instructions for reconstitution
Additional volumes and solution/suspension concentrations, which may be useful when fractional doses are required.

Vial size	Routes of administration	Amount of water to be added (mL)	Approximate cefuroxime concentration (mg/mL)**	Resulting product
750mg	intramuscular	3mL	216	Suspension
	intravenous bolus	at least 6mL	116	Solution
	intravenous infusion	at least 6mL	116	Solution
1.5g	intramuscular	6mL	216	Suspension
	intravenous bolus	At least 15mL	94	Solution
	intravenous infusion	15mL*	94	Solution

** Reconstituted solution to be added to 50 or 100ml of compatible infusion fluid (see information on compatibility, below)*
*** The resulting volume of the solution/suspension of cefuroxime in reconstitution medium is increased due to 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.

Following reconstitution with Water for Injections, chemical and physical in-use stability has been demonstrated for 24 hours at 2-8°C.

Compatibility
1.5g cefuroxime sodium constituted with 15mL Water for Injection may be added to metronidazole injection (500mg/100ml) and both retain their activity for up to 24 hours below 25°C.
1.5g cefuroxime sodium is compatible with azlocillin 1g (in 15ml) or 5g (in 50ml) 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 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:
- 0.9% w/v Sodium Chloride Injection BP

- 5% Dextrose Injection BP
- 0.18% w/v Sodium Chloride plus 4% Dextrose Injection BP5% dextrose containing 0.9% Sodium Chloride Injection
- 5% dextrose containing 0.45% Sodium Chloride Injection
- 5% dextrose containing 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 hours 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 mEqL) in 0.9% Sodium Chloride Injection.

In the absence of other compatibility studies, this medicinal product must not be mixed with other medicinal products apart from those listed as compatible above.

Cefuroxime should not be mixed in the syringe with aminoglycoside antibiotics.

The pH of 2.74% w/v Sodium Bicarbonate Injection BP considerably affects the colour of the solution and therefore this solution is not recommended for the dilution of Cefuroxime. However, if required, for patients receiving Sodium Bicarbonate Injection by infusion Cefuroxime 1.5 g may be introduced into the tube of the giving set.

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