Package leaflet: Information for the user

Cefuroxime 250mg Powder for Injection
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.
- 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 INJECTION 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 ARE GIVEN CEFUROXIME INJECTION

You must not be given Cefuroxime Injection:
- If you are allergic to any cephalosporin antibiotics
- If you have had a severe allergic 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 if you think that this applies to you. You must not be given Cefuroxime Injection.

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 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.

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 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:
- probenecid, which is a medicine used to treat "gout"
- "water tablets" (diuretics such as furosemide) - to help you go to the toilet
- aminoglycoside-type antibiotics
- 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.

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, 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 breast-feeding.

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 Injection contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially 'sodium-free'.

3. HOW CEFUROXIME INJECTION IS GIVEN

Cefuroxime Injection will 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 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 of 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.

INFORMATION FOR THE HEALTHCARE PROFESSIONAL
The following information is intended for medical or healthcare professionals only.

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			
Routes of administration	Physical State	Amount of water to be added (mL)	Approximate cefuroxime concentration (mg/mL)*
intramuscular	suspension	1 ml	216
intravenous bolus	solution	at least 2 ml	116
Intravenous infusion	solution	at least 2 ml*	116

* 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.

Reconstituted solutions may be diluted with:
- 10% dextrose
- 0.9% sodium chloride injection
- M/6 sodium lactate injection
- Ringer's injection
- Lactated Ringer's injection

Storing Cefuroxime Injection:
Keep vials in outer carton to protect from light.
Reconstituted solution: Chemical and physical stability has been demonstrated for 24 hours at 2°C – 8°C and for 8 hours at 25°C. 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 and would normally be no longer than 24 hours at 2-8°C unless reconstitution has taken place in controlled and validated aseptic conditions.

Incompatibilities
Solutions containing cefuroxime should not be mixed with or added to solutions containing other agents other than those listed opposite.

ACSI092F01

BIANCA/FRONT

ARTWORK PDF 1.5

PRODUCT CODE:
MOCKUP_LEA_CEFUROXIME 250MG GB IBI
PRODUCT NAME:
MOCKUP_LEA_CEFUROXIME 250MG GB IBI

SEPARATIONS:
BLACK

MEASURES (mm): **210 x 315 (105x52,5)**
TECHNICAL SPEC. : **ACSI092F01**
Thickness: **0,076 mm**
g/sq.mt: **60 gr/m²**
FONT TYPE: **Helvetica Lt std**
Size: **8 pt** - Spacing: **9,5 pt**

ACS DOBFAR SpA

DATE	OPERATOR	DRAFT
26/4/2023	RI007M	02

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ACS-T-v.09-2019

Please ensure artwork is checked with this settings: Print Production >> Output Preview >> Overprint Preview turned on and Color profile simulation set to "Coated FOGRA 39"

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, Cefuroxime Injection 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*)
- **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 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 or nurse immediately if you get any of these symptoms.

Common side effects (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 (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
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 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 printed on the label and carton after EXP. The expiry date refers to the last day of that month.

Keep vials in outer carton to protect from light.

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 Injection contains
- The active substance is Cefuroxime 250mg
- Your medicine contains no other ingredients

What Cefuroxime Injection looks like and contents of the pack:
Cefuroxime Injection is a white or almost white powder in a glass vial.
Each vial contains 250mg of Cefuroxime.
Each carton contains 1, 5, 10, 20 or 50 vials. Not all pack sizes may be marketed.

Marketing Authorisation Holder:
Istituto Biochimico Italiano G. Lorenzini SpA,
via Fossignano 2,
04011 Aprilia (LT),
Italy

Manufacturer:
ACS Dobfar S.p.A.
Nucleo Industriale S.Atto,
S.Nicoló a Tordino,
64100 – Teramo, Italy

This leaflet was last revised in April 2023.

The pH of 2.74% w/v sodium bicarbonate injection BP considerably affects the colour of solutions and therefore this solution is not recommended for the dilution of cefuroxime powder for injection. However, if required, for patients receiving sodium bicarbonate injection by infusion, the cefuroxime powder for injection may be introduced into the tube of the giving set.

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

ACSI092F01

VOLTA/BACK

ARTWORK PDF 1.5

PRODUCT CODE:
MOCKUP_LEA_CEFUROXIME 250MG GB IBI
PRODUCT NAME:
MOCKUP_LEA_CEFUROXIME 250MG GB IBI

SEPARATIONS:
BLACK

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Package leaflet: Information for the user

Cefuroxime 250mg Powder for Injection
Cefuroxime sodium

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- If you are allergic to any cephalosporin antibiotics
- If you have had a severe allergic 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 if you think that this applies to you. You must not be given Cefuroxime Injection.

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 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.

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.

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Cefuroxime Injection contains sodium
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3. HOW CEFUROXIME INJECTION IS GIVEN

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The correct dose 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.

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Talk to your doctor if this applies to you.

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- **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).
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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 or nurse immediately if you get any of these symptoms.

Common side effects (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 (may affect up to 1 in 100 people)
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Other side effects
Other side effects have occurred in a very small number of people but their exact frequency is unknown:
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- 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*)
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5. HOW TO STORE CEFUROXIME INJECTION

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Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is printed on the label and carton after EXP. The expiry date refers to the last day of that month.

Keep vials in outer carton to protect from light.

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.

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- The active substance is Cefuroxime 250mg
- Your medicine contains no other ingredients

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Each vial contains 250mg of Cefuroxime.
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Marketing Authorisation Holder:
Istituto Biochimico Italiano G. Lorenzini SpA,
Via Fossignano 2,
04011 Aprilia (LT), Italy

Manufacturer:
ACS DOBFAR SpA,
Via A. Fleming, 2
37135 Verona – Italy

This leaflet was last revised in April 2023.

INFORMATION FOR THE HEALTHCARE PROFESSIONAL
The following information is intended for medical or healthcare professionals only.

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

Routes of administration	Physical State	Amount of water to be added (mL)	Approximate cefuroxime concentration (mg/mL)*
intramuscular	suspension	1 ml	216
intravenous bolus	solution	at least 2 ml	116
Intravenous infusion	solution	at least 2 ml*	116

* 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.

Reconstituted solutions may be diluted with:
- 10% dextrose
- 0.9% sodium chloride injection
- M/6 sodium lactate injection
- Ringer's injection
- Lactated Ringer's injection

Storing Cefuroxime Injection:
Keep vials in outer carton to protect from light.
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Incompatibilities
Solutions containing cefuroxime should not be mixed with or added to solutions containing other agents other than those listed opposite.

The pH of 2.74% w/v sodium bicarbonate injection BP considerably affects the colour of solutions and therefore this solution is not recommended for the dilution of cefuroxime powder for injection. However, if required, for patients receiving sodium bicarbonate injection by infusion, the cefuroxime powder for injection may be introduced into the tube of the giving set.

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

D02123LEA

BIANCA/FRONT

ARTWORK PDF 1.5

PRODUCT CODE: **F5381715**
PRODUCT NAME: **I. CEFUROX 250MG IBI GB**

SEPARATIONS: BLACK

Font Type: **Helvetica Lt std**
Font Size: **8** Spacing: **9,5**
CUSTOMER CODE: **n.a.**
SITE SICURITY CODE: **F5381715**

ACS DOBFAR SPA
TECH. LAYOUT: **D02123LEA.V5**
Size (mm): **420 x 297** *(fold 120 x 43)*
CUTTING PROFILE: **D02123LEA**
Date: **20/11/2023** Draft: **01** (RI007M)

DATE	OPERATOR	DRAFT
30/01/2024	RI007M	06

Diecut

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INFO_v01-2020

Please ensure artwork is checked with this settings: Print Production >> Output Preview >> Overprint Preview turned on and Color profile simulation set to "Coated FOGRA 39"

420 mm

297 mm

D02123LEA

VOLTA/BACK

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