Package leaflet: Information for the user

Zinacef
250 mg powder for solution or suspension for injection
750 mg powder for solution or suspension for injection
1.5g 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 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 Zinacef is and what it is used for

Zinacef 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.*

Zinacef is used to treat infections of:

- the lungs or chest
- the urinary tract
- the skin and soft tissue
- the abdomen

Zinacef 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 Zinacef during your treatment.

2. What you need to know before you are given Zinacef

You must not be given Zinacef:
- **if you are allergic** to **any cephalosporin antibiotics** or any of the other ingredients of Zinacef (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).

➔ **Tell your doctor before** you start on Zinacef if you think that this applies to you. You must not be given Zinacef.

Take special care with Zinacef

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 Zinacef. 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 Zinacef.

If you need a blood or urine test
Zinacef 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 Zinacef.

Other medicines and Zinacef
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 Zinacef 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 Zinacef.

Contraceptive pills
Zinacef may reduce the effectiveness of the contraceptive pill. If you are taking the contraceptive pill while you are being treated with Zinacef 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
Tell your doctor before you are given Zinacef:
- 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 Zinacef against the risk to your baby.

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

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

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

750 mg vial:
This medicine contains 42 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 2.1 % of the recommended maximum daily dietary intake of sodium for an adult.

1.5 g vial:
This medicine contains 83 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 4.15 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How Zinacef is given

Zinacef 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 Zinacef 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 Zinacef 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 Zinacef per day divided in three or four doses.

Adults and adolescents
750 mg to 1.5 g of Zinacef 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.

4. Possible side effects

Like all medicines, Zinacef can cause side effects, although not everybody gets them.

Conditions you need to look out for
A small number of people taking Zinacef 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 Zinacef include:

- **fungal infections** on rare occasions, medicines like Zinacef 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 Zinacef for a long time.

- **severe diarrhoea (*Pseudomembranous colitis*).** Medicines like Zinacef 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 and serum creatinine in the blood.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Zinacef

- Do not store above 25°C.
- Keep vial in the outer carton to protect from light.
- Single use only.
- Discard any remaining contents after use.
- Chemical and physical in-use stability of the reconstituted solution has been demonstrated for 5 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 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 (etc) has taken place in controlled and validated aseptic conditions.

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.

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 to protect the environment.

6. Contents of the pack and other information

What Zinacef contains

- The active substance is 1.5 g, 750 mg or 250 mg of cefuroxime (present as cefuroxime sodium).
- There are no other ingredients. However, see section 2 for further important information about sodium (present as cefuroxime sodium).

What Zinacef looks like and contents of the pack

Zinacef 1.5 g, 750 mg or 250 mg is supplied as white to cream powder in moulded glass vials with a rubber bung and flip-off cap. Each individual vial is packed in a carton. Your doctor, pharmacist or nurse will make the injection up with Water for Injections for your muscle or vein injection. When made up for injection into a muscle, it becomes off-white and opaque. When made up for injection into a vein, it is yellowish.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: GlaxoSmithKline (Ireland) Limited, 12 Riverwalk, Citywest Business Campus, Dublin 24
Manufacturer: GlaxoSmithKline Manufacturing S.p.A., Via A. Fleming 2, 37135 Verona, Italy.

This medicinal product is authorised in the Member States of the EEA under the following names:

250 mg powder for solution for injection or infusion
Austria – Curocef
Denmark, Finland, Hungary, Ireland, Lithuania, Malta, Norway, Sweden, United Kingdom – Zinacef
Italy – Curoxim
France - Zinnat

750 mg powder for solution for injection or infusion
Austria – Curocef
Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, Greece, Hungary, Iceland, Ireland, Luxembourg, Malta, Norway, Poland, Romania, Slovenia, Sweden, United Kingdom – Zinacef
France - Zinnat

1.5 g powder for solution for injection or infusion
Austria - Curocef
Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland Greece, Hungary, Iceland, Ireland, Lithuania, Luxembourg, Norway, Poland, Slovenia, Sweden, United Kingdom - Zinacef
France - Zinnat

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1.5g powder for solution for injection or infusion
Cefuroxime

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			
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			
250 mg	intramuscular intravenous bolus intravenous infusion	suspension solution solution	1 mL at least 2 mL at least 2mL*	216 116 116
	750 mg powder for solution for injection or infusion			

750 mg	intramuscular intravenous bolus intravenous infusion	suspension solution solution	3 mL At least 6 mL At least 6 mL	216 116 116
1.5 g powder for solution for injection or infusion				
1.5 g	intramuscular intravenous bolus intravenous infusion	suspension solution solution	6 mL at least 15 mL15 mL*	216 94 94

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

Compatibility

1.5 g cefuroxime sodium constituted with 15 mL Water for Injection may be added to metronidazole injection (500 mg/100 mL) and both retain their activity for up to 24 hours below 25 °C.

1.5 g cefuroxime sodium is compatible with azlocillin 1 g (in 15 mL) or 5 g (in 50 mL) 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 BP
5% Dextrose and 0.9% w/v Sodium Chloride Injection BP
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 0.9% w/v Sodium Chloride Injection BP 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 IV infusion with:

Heparin (10 and 50 units/ml) in 0.9% w/v Sodium Chloride Injection; Potassium Chloride (10 and 40 mEqL) in 0.9% Sodium Chloride Injection.