PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Cefuroxime 50 mg

powder for solution for injection

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, pharmacist 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, pharmacist 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
2. What you need to know before you are given Cefuroxime
3. How Cefuroxime is administered
4. Possible side effects
5. How to store Cefuroxime
6. Contents of the pack and other information

1. WHAT CEFUROXIME IS AND WHAT IT IS USED FOR

Cefuroxime contains the active substance, cefuroxime (as cefuroxime sodium) which belongs to a group of antibiotics called cephalosporins. Antibiotics are used to kill the bacteria or germs that cause infections.

This medicine will be used if you are **undergoing eye surgery because of cataract** (cloudiness of the lens).

Your ophthalmic surgeon will administer this medicine **by injection into the eye** at the end of cataract surgery in order to **prevent eye infection.**

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN CEFUROXIME

Do not use Cefuroxime
If you are **allergic** to **cefuroxime** or to any of the **cephalosporin type antibiotics**.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before you are given Cefuroxime:
- if you have had a reaction to **other antibiotics** such as penicillin;
- if you have previously had an **antibiotic resistant infection** e.g. Methicillin-resistant *Staphylococcus aureus*;
- if you are at risk of a **severe infection**;
- if you have been diagnosed with a **complicated cataract**;
- if a **combined eye surgery** is planned;
- if you have severe **thyroid disease**.

Cefuroxime should be administered in aseptic conditions (meaning clean and germ free) of cataract surgery.

One vial of Cefuroxime must be used for one patient only.

Other medicines and Cefuroxime
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding
Cefuroxime can be used during pregnancy and breast-feeding.

3. HOW CEFUROXIME IS ADMINISTERED

Cefuroxime injections will be administered, as an injection into the eye, by an ophthalmic surgeon at the end of cataract surgery.

Cefuroxime is supplied as a sterile powder and is dissolved in saline solution for

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Cefuroxime 50 mg

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The following information is intended for healthcare professionals only:

Incompatibilities
This medicinal product must not be mixed with other medicinal products except those mentioned below [sodium chloride 9 mg/ml (0.9%) solution for injection].

How to prepare and administer Cefuroxime
Single-use vial for intracameral use only.

Cefuroxime must be administered after reconstitution by intraocular injection in the anterior chamber of the eye (intracameral injection), by an ophthalmic surgeon, in the recommended aseptic conditions of cataract surgery.

The reconstituted solution should be visually inspected and should only be used if it is a clear, colourless to yellowish solution free from visible particles.
The product should be used immediately after reconstitution and not reused. The medicinal product should be discarded if particles are visible in the solution.

The recommended dose for cefuroxime is 1 mg in 0.1 ml sodium chloride 9 mg/ml (0.9%) solution for injection.

THE RECOMMENDED DOSE MUST NOT BE EXCEEDED.

Vial is for single use only.
Each vial should only be used for the treatment of a single eye. The flag label of the vial should be stuck on the patient's file, as applicable.

injection before it is administered.

If you are given too much, or too little Cefuroxime
Your medication will usually be given by the health professional. If you think you may have received too little or too much medicine, please tell your doctor or nurse.

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

4. POSSIBLE SIDE EFFECTS

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

Speak to a doctor or nurse immediately if you get any of these symptoms.
- Serious allergic reaction which causes a **raised itchy skin rash** (urticaria or 'hives'), **difficulty in breathing**, or **dizziness**. The side effect is very rare (may affect up to 1 in 10,000 people).
- Blurry or wavy vision near or in the center of your field of vision (macular oedema). The frequency of this side effect is not known (cannot be estimated from the available data).

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

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.

Store the vial in the original package in order to protect from light.
For single use only.

After reconstitution: the product should be used immediately.

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 (as cefuroxime sodium).
- Each vial contains 50 mg of cefuroxime. After reconstitution, 0.1 ml solution contains 1 mg of cefuroxime.
- There are no other ingredients.

For details on the required medical devices and solvent, please refer to "How to prepare and administer Cefuroxime".

What Cefuroxime looks like and contents of the pack
Cefuroxime is a white to almost white powder for solution for injection, supplied in a clear glass vial.

Each box contains 1 or 10 or 20 vials together with the corresponding amount of 5-micron sterile filter needles.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
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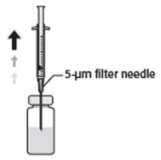
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To prepare Cefuroxime for intracameral administration, please adhere to the following instructions:

	1. Check the integrity of the flip-off cap before withdrawing it.
	2. Before inserting a sterile needle, disinfect the outer part of the rubber stopper of the vial.
	3. Push the sterile needle vertically into the centre of the vial stopper, keeping the vial in an upright position. Aseptically inject into the vial 5 ml of sodium chloride 9 mg/ml (0.9%) solution for injection.
	4. Shake gently until the solution is clear and free from visible particles.

	5. Assemble a sterile needle (18G x 1½", 1.2 mm x 40 mm) with 5-micron filter (acrylic copolymer membrane on a non-woven nylon) onto a 1 ml sterile syringe. Then, push this 1 ml sterile syringe vertically into the centre of the vial stopper, keeping the vial in an upright position.
	6. Aseptically withdraw at least 0.1 ml of the solution. The remaining reconstituted solution in the vial (4.9 ml) should be discarded.
	7. Disconnect the micron filter needle from the syringe and the syringe should be assembled with an appropriate anterior chamber cannula.
	8. Carefully expel the air from the syringe by slowly depressing the plunger so that the plunger tip aligns with the line that marks 0.1 ml on the syringe. The syringe is ready for injection.

After use, the remaining reconstituted solution must be discarded. It must not be kept for subsequent use.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.