PACKAGE LEAFLET

Package leaflet: Information for the patient

Ximaract 50mg 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 Ximaract is and what it is used for

Ximaract 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 a 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 Ximaract

Do not use Ximaract if you are **allergic** to **cefuroxime** or to any of the **cephalosporin type antibiotics** or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before you are given Ximaract:
- 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 **combined eye surgery** is planned;
- if you have severe **thyroid disease**.

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

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

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

Pregnancy and breast-feeding
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.

You will only be given Ximaract if your doctor thinks it is clearly necessary.

3. How Ximaract is administered

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

Ximaract is supplied as a sterile powder and is dissolved in saline solution for injection before it is administered.

If you are given too much, or too little Ximaract
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 at: 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 Ximaract

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

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

For single use only.

After reconstitution the product should be used immediately.
Any remaining reconstituted solution must be discarded.

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 Ximaract 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.

To prepare the product for intracameral administration, a **sterile needle (18G x 1½", 1.2 mm x 40 mm) with 5-micron filter (acrylic co-polymer membrane)** must be used.

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

What Ximaract looks like and contents of the pack
Ximaract is a white to almost white powder for solution for injection, supplied in a clear, transparent glass vial.
Each box contains 1 vial, 10 vials, 25 vials or 1 vial together with 1 sterile filter needle, 10 vials together with 10 sterile filter needles, 25 vials together with 25 sterile filter needles. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder
Bausch & Lomb UK Limited,
Bausch & Lomb House,
106 London Road ,
Kingston-Upon-Thames,
Surrey, UK, KT2 6TN

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

PRESPACK Sp. z o.o.
ul. Sadowa 38
60-185 Skórzewo
Poland

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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 Ximaract

Single-use vial for intracameral use only.

Ximaract 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.

To prepare Ximaract for intracameral administration, please adhere to the following instructions:

1. Check the integrity of the flip-off cap before withdrawing it.
2. Disinfect the surface of the rubber stopper before step 3.
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, colourless to yellowish and free from visible particles.
5. Assemble a sterile needle (18G x 1½", 1.2 mm x 40 mm) with 5-micron filter (acrylic co-polymer membrane) 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. Discard the remaining reconstituted solution (4.9 ml) in the vial.
7. Disconnect 5-micron filter needle from the syringe and attach a sterile anterior chamber cannula to the syringe.
8. Carefully expel the air from the syringe and expel excess drug 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, discard the remaining reconstituted solution. Do not keep it for subsequent use.
Any unused product or waste material should be disposed of in accordance with local requirements.
Discard used needles in a sharps container.