LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Ximaract
(cefuroxime sodium)

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Ximaract

(cefuroxime sodium)

Powder for solution for injection; 50 mg

This is a summary of the public assessment report (PAR) for Ximaract. It explains how Ximaract was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Ximaract.

For practical information about using Ximaract, patients should read the package leaflet or contact their doctor or pharmacist.

What is Ximaract and what is it used for?

Ximaract is a medicine with 'well-established use'. This means that the medicinal use of the active substance of Ximaract is well established in the European Union for at least ten years, with recognised efficacy and an acceptable level of safety.

Ximaract can be used by patients who undergo eye surgery because of a cataract (cloudiness of the lens). The ophthalmic surgeon will administer Ximaract by injection into the eye at the end of cataract surgery in order to prevent eye infection.

How does Ximaract work?

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.

How is Ximaract used?

The pharmaceutical form of Ximaract is powder for solution for injection. The powder will be dissolved in a saline solution before it is injected into the eye.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

What benefits of Ximaract have been shown in studies?

As cefuroxime sodium is a well-known substance, and its use when undergoing eye surgery because of cataract is well established, the applicant presented data from the scientific literature. The literature provided confirmed the efficacy and safety of cefuroxime sodium in use when undergoing eye surgery because of cataract.

What are the possible side effects of Ximaract?

For the full list of all side effects reported with Ximaract, see section 4 of the package leaflet. For the full list of restrictions, see the package leaflet.

Why is Ximaract approved?

The use of Ximaract when undergoing eye surgery because of cataract is well-established in medical practice and documented in the scientific literature. No new or unexpected safety concerns arose from these applications. Therefore, the Medical Products Agency in Sweden decided that Ximaract's benefits are greater than its risks and recommended that it be approved for use.

What measures are being taken to ensure the safe and effective use of Ximaract?

A risk management plan has been developed to ensure that Ximaract is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Ximaract, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Ximaract

The marketing authorisation for Ximaract was granted on 2016-08-24 in Sweden.

The full PAR for Ximaract can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Ximaract, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2016-08.