APROK 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, or 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, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. WHAT APROK IS AND WHAT IT IS USED FOR

The full name of your medicine is Aprok 50 mg, powder for solution for injection. It is called Aprok in this leaflet.

This medicine contains 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.

You will be given this medicine if you are having eye surgery because of cataract (cloudy lens). Your ophthalmic surgeon will give you this medicine by injection into the eye at the end of the surgery to prevent eye infection.

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

Do not use APROK
- If you are allergic (hypersensitive) to cefuroxime or to any of the cephalosporin type of antibiotics.

Warnings and precautions
Talk to your doctor, or pharmacist or nurse before you are given APROK:
- if you are allergic to other antibiotics such as penicillin,
- if you are at risk of an infection due to bacteria called MRSA (Methicillin-resistant *Staphylococcus aureus*),
- if you have a high risk of infection,
- if you have been told you have a complicated cataract,
- if a combined eye surgery is planned,
- if you have severe thyroid disease (a condition which affects the working of the thyroid).

APROK is only given as an injection into the eye (intracameral injection).

APROK should be given in aseptic (meaning clean and germ free) conditions of cataract surgery.
One vial (bottle) of APROK must be used for one patient only.

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

Pregnancy, breast-feeding and fertility
- 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 APROK if the benefits outweigh the potential risks.

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

3. HOW APROK IS USED

Your surgeon will inject Aprok at the end of your surgery.

Aprok is a sterile powder, which is dissolved in saline solution for injection before it is given.

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

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

4. POSSIBLE SIDE EFFECTS

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

The following side effect is very rare (may affect up to 1 in 10,000 people):
Serious allergic reaction which causes difficulty in breathing or dizziness.

The following side effect is reported with a frequency "Not known" (cannot be estimated from the available data):
- Macular oedema (blurry or wavy vision near or in the centre of your field of vision).

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly on the details below. By reporting side effects you can help provide more information on the safety of this medicine.

HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie

5. HOW TO STORE APROK

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.

Store below 25ºC. Keep the vial in the outer carton, 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 APROK 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.

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

Each box contains 1 or 10 or 20 vials, or 10 vials together with 10 sterile filter needles. Not all box sizes may be available.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder:
LABORATOIRES THEA
12 rue Louis Blériot
63017 CLERMONT-FERRAND Cedex 2
France

Manufacturer:
BIOPHARMA S.R.L.
Via Delle Gerbere, 22/30
(loc. S. PALOMBA)
00134 ROMA (RM)
Italy

This medicine is authorised in the Member States of the EEA under the following names:
Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Italy, Iceland, Luxembourg, The Netherlands, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Sweden, United Kingdom ... APROKAM
Cyprus, Greece, Spain ..... PROKAM
Ireland .....APROK

This leaflet was last revised in August 2019.

If you would like any more information, or would like the leaflet in a different format, please contact Medical Information at THEA Pharmaceuticals Ltd/THEA Pamex, telephone number +44 (0) 345 521 1290.

The following information is intended for medical or healthcare professionals only:

Incompatibilities
No incompatibility with most commonly used products in cataract surgery was reported in literature. 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 APROK

Single-use vial for intracameral use only.

APROK 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 colourless to yellowish solution free from visible particles.
The product should be used immediately after reconstitution and not reused.

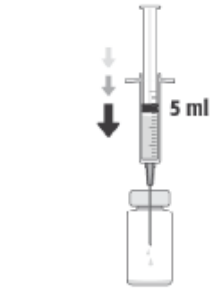
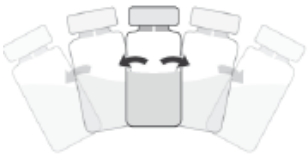
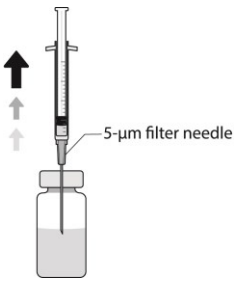
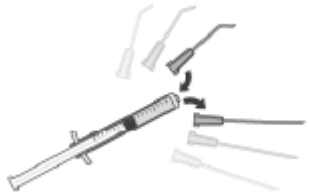
The recommended dose for cefuroxime is 1 mg in 0.1 ml sodium chloride 9 mg/ml (0.9%) solution for injection.

DO NOT INJECT MORE THAN THE RECOMMENDED DOSE.

Vial is for single use only.

One vial for one patient only. Stick the flag label of the vial on the patient file.

To prepare APROK 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 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 (the sterile needle with 5-micron filter may be provided in the box). 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.
	7. Disconnect the needle from the syringe and attach a sterile anterior chamber cannula to the syringe.
	8. Carefully expel the air from the syringe and adjust the dose to the 0.1 ml mark on the syringe. The syringe is ready for injection.
After use, discard the remaining of the 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.