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XXXXXXXX

Aprokam 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 APROKAM IS AND WHAT IT IS USED FOR

- Aprokam contains an 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 APROKAM

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

Warnings and precautions

Talk to your doctor or, pharmacist or nurse before using Aprokam:
- if you are allergic to other antibiotics such as penicillin,
- if you are at risk of an infection due to bacteria called Methicillin-resistant *Staphylococcus aureus*,
- if you are at risk of a severe risk of infection,
- if you have been diagnosed a complicated cataract,
- if a combined eye surgery is planned,
- if you have severe thyroid disease.

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

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

Other medicines and Aprokam

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 Aprokam if the benefits outweigh the potential risks.

APROKAM contains sodium

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

3. HOW APROKAM IS ADMINISTERED

- Aprokam injections will be administered by an ophthalmic surgeon at the end of cataract surgery.
- Aprokam 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, Aprokam.

Your medication 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.

Please turn

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 Aprokam

Single-use vial for intracameral use only.

Aprokam 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.

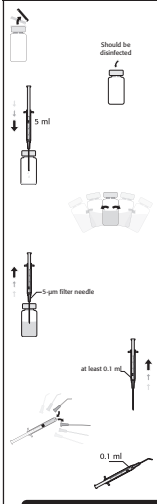
The product should be used immediately after reconstitution and not reused.

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 Aprokam 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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Aprokam 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 via the Yellow Card Scheme.
Web site: 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 APROKAM

Keep this medicine out of the sight and reach of children.

Do not use Aprokam 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 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.

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 to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

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

Each box contains one or ten or twenty vials, or ten vials together with ten sterile filter needles. Not all pack size may be marketed.

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

This medicinal product is authorised in the Member States of the EEA under the following names:
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United Kingdom.....APROKAM
Cyprus, Greece, Spain.....PROKAM
Ireland.....APROK

This leaflet was last approved in 04/2019.

If you would like any more information, or would like the leaflet in a different format, please contact Medical Information at
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