

MODULE-1
ADMINISTRATIVE INFORMATION FOR AXACOMOCATE
PATIENT INFORMATION LEAFLET (PIL)

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to your doctor if your eyes do not feel better or if they feel worse after 2 days

What is in this leaflet:

- 1. What AXACOMOCATE is and what it is used for**
- 2. What you need to know before you use AXACOMOCATE**
- 3. How to use AXACOMOCATE**
- 4. Possible side effects**
- 5. How to store AXACOMOCATE**
- 6. Contents of the pack and other information**

1. What AXACOMOCATE is and what it is used for

Axacomocate contains sodium cromoglicate which belongs to a group of medicines called anti-allergics.

It works by stopping the release of the natural substances in your eyes that can lead to an allergic reaction. Signs of an allergic reaction include itchy, watery, red or inflamed eyes and puffy eyelids.

This medicine is used for the prevention and treatment of eye allergies.

These allergies can happen:

- At any time of the year and is called ‘perennial allergic conjunctivitis’.
- In different seasons of the year caused by different pollens.

This is called ‘seasonal allergic conjunctivitis’ or hay fever.

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2. WHAT YOU NEED TO KNOW BEFORE YOU USE AXACOMOCATE

Do not use this medicine

- If you are allergic (hypersensitive) to sodium cromoglicate or any of the other ingredients of this medicine (listed in Section 6).

Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat, tongue and worsening of redness, itching or swelling of the eye or eyelid.

Do not use this medicine if the above applies to you. If you are not sure, talk to your doctor or pharmacist before using this medicine.

Warnings and precautions

Talk to your doctor or pharmacist before using this medicine if you wear soft contact lenses. You should not wear contact lenses while using these drops.

If you are not sure if the above applies to you, talk to your doctor or pharmacist before using this medicine.

Other medicines and this medicine

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 taking this medicine.

Driving and using machines

You may have blurred eyesight straight after using this medicine.

If this happens, do not drive or use any tools or machines until you can see clearly.

This medicine contains benzalkonium chloride.

Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards.

Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

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3. How to use AXACOMOCATE

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How to use this medicine

- Wash your hands.
- Before using the medication for the first time, be sure that the tamper-proof seal on the bottle neck is unbroken. A gap between the bottle and the cap is normal for an unopened bottle.
- Remove the cap from the bottle.
- Tilt your head back.
- Squeeze one or two drops inside the lower lid without touching your eye.
- Close your eye.
- Wipe away any excess liquid from the eyes with a clean tissue.
- Always put the cap back on the bottle as soon as you have used it.
- Repeat in the other eye if needed.

How much to use

- One or two drops in each eye four times a day, or as directed by your doctor.
- If your symptoms worsen or do not improve, talk to your doctor or pharmacist.

If you use more of this medicine than you should

Contact your doctor if you use the eye drops more frequently than the recommended dose, or continuously for more than three months.

If you forget to use this medicine

If you forget a dose, use your drops as soon as you remember.

However, if it is nearly time for your next dose, skip the missed dose. Do not use a double dose to make up for a forgotten dose.

If you stop using this medicine

You should keep using these drops if you are still around the things that you are allergic to. If you stop using this medicine your allergy symptoms may come back.

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

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4. POSSIBLE SIDE EFFECTS

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

Stop using this medicine and see a doctor as soon as possible if:

- The itching, redness or swelling gets worse. You may be allergic to this medicine.

Talk to your doctor or pharmacist if any of the side effects get serious or last longer than a few days, or if you notice any side effects not listed in this leaflet:

- Stinging or burning in your eyes or blurring of eyesight. This should only last for a short time and occurs immediately after using the eye drops.
- Mild eye irritation.

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.

5. How to store AXACOMOCATE

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

Store below 30°C. Protect from light. Do not refrigerate or freeze.

This medicine is sterile when you buy it, so you must not keep it for more than four weeks after opening the bottle.

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. CONTENT OF THE PACK AND OTHER INFORMATION

What **AXACOMOCATE** contains

- The active substance is Sodium Cromoglicate BP.
- The other ingredients are Glycerine BP, Disodium Edetate BP, Polysorbate 80 BP, Benzalkonium chloride solution BP, Sodium Hydroxide BP & Water for Injection BP

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What AXACOMOCATE looks like and contents of the pack

Clear pale yellow solution

Pack: 10 mL LDPE vial packed in a unit carton along with pack insert.