# Package leaflet: Information for the patient Allercrom 2% w/v Eye Drops

Sodium Cromoglicate

# Read all of this leaflet carefully before you start using 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 14 days.

### What is in this leaflet

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

### 1. What Allercrom is and what it is used for

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

Sodium cromoglicate has an anti-inflammatory action and reduces redness, soreness and itching in eyes affected by allergic conditions like hayfever when used regularly during the course of treatment.

These symptoms occur usually in the late spring or early summer when pollen from grasses or trees comes into contact with the eyes of people who are sensitive to them. This condition is sometimes called 'hayfever eyes' or by its medical term: seasonal allergic conjunctivitis.

If you suffer from hayfever, you can also help control your symptoms by trying to ensure low exposure to pollen when hayfever symptoms are expected. For example, keep windows closed, do not cut grass, stay indoors as much as possible.

## 2. What you need to know before you use Allercrom

### Do not use Allercrom:

• If you or your child are allergic to sodium cromoglicate or any of the other ingredients of this medicine (listed in section 6).

Signs of 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.

- If your child is under 6 years of age.
- If you or your child are sensitive to eye drops containing sodium cromoglicate, benzalkonium chloride or disodium edetate.
- For other allergic eye symptoms (not caused by hayfever). Other things in everyday life can start allergies causing eye symptoms in certain people.
   For example contact with animals including pets, house dust mites, other particles and chemicals. Talk to your pharmacist or doctor.

Do not use Allercrom if the above applies to you. If you are not sure talk to your doctor or pharmacist before using these eye drops.

# Warnings and precautions

You must be confident that you or your child's irritated eyes are caused by hayfever, or have been previously diagnosed by your doctor to suffer from hayfever: You can be sure allergic eyes are caused by hayfever if:

- Both eyes are affected
- You also have a runny or blocked nose
- Your eyesight is not affected
- You know you suffer from hayfever and your symptoms coincide with the times of year when grass or tree pollen is high.

But if you or your child have:

- No nose symptoms
- Only one eye is affected
- Your sight is affected

Or if the eye symptoms:

- occur at the wrong time of year for hayfever
- are likely to be caused by another allergy, e.g. a pet or dust mite allergy.

Then you cannot be sure that the condition is due to hayfever and you should see your doctor or pharmacist before you use 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 Allercrom

Tell your doctor or pharmacist if you are using, have recently used or might use 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**

This medicine can cause blurred vision for a few minutes after use. If this happens, do not drive or operate machines until you can see normally again.

### Allercrom contains benzalkonium chloride:

This medicine contains 0.10 mg /ml benzalkonium chloride as preservative. 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.

#### 3. How to use Allercrom

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.

## Adults (including the elderly) and children over 6 years

One or two drops administered into each eye four times daily.

## Children under 6 years

This medicine should not be used in children under 6 years of age.

If you have any questions concerning the use of these drops in a child, or are unsure if the child has allergic eyes, you should seek advice from your doctor or pharmacist.

# If your eyes are no better after 2 days of using the eye drops, see your doctor or pharmacist.

It is best to use your eye drops regularly every day while high pollen levels are expected, to keep your eye condition controlled. If you find you need to use them continuously for more than 14 days, then check with your pharmacist or doctor before continuing.

#### Instructions for use

- Wash your hands before using the drops.
- Tilt your head back and carefully pull down your lower eyelid.
- Without touching the eyelid with the tip of the dropper, put one or two
  drops into your lower lid and then blink a few times to make sure your
  whole eye is covered by the liquid.
- Replace the cap securely on the bottle.

Be careful not to touch the tip of the bottle on your eye or on any other surface. Ocular Solutions, if handled wrongly, can become contaminated by common bacteria and cause eye infections. If you do develop any intercurrent ocular condition (e.g. trauma, ocular surgery or infection) whilst using this product, see your doctor immediately.

## If you use more of Allercrom than you should

Contact your doctor if you use the eye drops more frequently than the recommended dose.

## If you forget to use Allercrom

If you miss a dose, use the drops as directed above and then continue your normal course of treatment.

Do not take a double dose to make up for a forgotten dose.

# If you stop using Allercrom

Even if your symptoms have got better, you should keep using these drops if you are still around the things that you are allergic to. Allercrom can prevent you getting an allergic reaction so if you stop using it your allergy symptoms may come back.

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

### 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. All medicines can cause allergic reactions, although serious allergic reactions are very rare.

Stop taking this medicine and see your doctor straight away if you get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash, or itching (especially affecting your whole body). You may be allergic to these drops.

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 occur immediately after using the eye drops.
- eye irritation.

## Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at <a href="https://www.mhra.gov.uk/yellowcard">www.mhra.gov.uk/yellowcard</a> 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 Allercrom

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

Do not use the eye drops after the expiry date which is stated on the bottle and on the carton the bottle is packed in. The expiry date refers to the last day of that month.

# Discard the bottle 28 days after opening, even if there is solution remaining.

Do not store the eye drops above 30°C.

Keep them in the original container and out of direct sunlight.

Keep bottle in outer carton.

Replace cap securely after use.

## 6. Content of the pack and other information

### What Allercrom contains

The active substance is Sodium Cromoglicate 2% w/v.

The other excipients are sodium chloride, disodium edetate, polysorbate 80, benzalkonium chloride and water for injections.

## What Allercrom looks like and contents of the pack

This medicine is a clear, colourless solution supplied in a 5ml or 10ml BFS Vial and closed with a screw cap. Not all pack sizes may be marketed.

## **Marketing Authorization Holder and Manufacturer**

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Call + 44(0) 1489 565222 for help.

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MODE OF USE



Tighten the cap on the nozzle.



The spike in the cap will pierce the tip of the bottle.



Tilt head backwards.

Dispense drops with gentle pressure. Do not touch dropper tip to the surface of the eye.