

Opticrom Hayfever Relief 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 your doctor if you do not feel better or if you feel worse after 14 days.

What is in this leaflet:

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

1. What this medicine is and what it is used for

This medicine 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.

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.

2. What you need to know before you use this medicine

Do not use this medicine

- 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 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.
- If your child is under 6 years of age.
- 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 this medicine 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 your 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 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 this medicine.

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

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 may interfere with your ability to drive and use 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.

This medicine contains 100 micrograms of benzalkonium chloride in each ml of solution.

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 this medicine

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 question 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, check with your pharmacist or doctor before continuing.**

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.



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 use more of this medicine than you should

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

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.

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 occur 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. You can also report side effects directly via the Yellow Card Scheme (Website: 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 this medicine

Keep 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.

This medicinal product does not require any special storage conditions before opening the bottle. After opening the bottle, do not store above 25°C. 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. Contents of the pack and other information

What this medicine contains

- The active substance is sodium cromoglicate. Each 1ml of eye drops contains 20mg of sodium cromoglicate (2.0% w/v). One drop contains 0.7mg of sodium cromoglicate.
- The other ingredients are disodium edetate, benzalkonium chloride and water for injections.

What this medicine looks like and contents of the pack

This medicine is a clear colourless to pale yellow solution supplied in either a 5ml or 10ml plastic dropper bottle with a tamper-proof cap.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Aspire Pharma Limited
Unit 4, Rotherbrook Court
Bedford Road
Petersfield
Hampshire, GU32 3QG
United Kingdom

Manufacturer

Rafarm S.A.
Agiou
Louka str.
19002
Paiania
Attiki
Greece

Distributor

Sanofi
410 Thames Valley Park Drive
Reading
Berkshire
RG6 1PT, UK

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Packaging Information:

Product Name: Opticrom hayfever
PI No:35533.0031
Dimensions: 135mm x550mm
Type:Leaflet
Version No:3.2
Date amended:4.10.19
Font:Helvetica
Average font size: 10
Reason for change:Sanofi change of address
Software:Adobe Indesign CS6
Created by: TP



**Colour:
Pantone:**

PMS Black



1010412-P3.2 - Opticrom Hayfever Eye Drops

Plant: GREAT-BRITAIN THIRD PARTY
Packaging material code: 1010412-P3.2
Packaging material name: Opticrom Hayfever Eye Drops
Second packaging material code:
VISTAlink folder number: 4191242
VISTAlink PDF version: 1

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Reason	Signed by	Date
Market health authorities approval	Tracey Abbott (UK regulatory team)	15/12/2021 19:07:29