

**PACKAGE LEAFLET:
INFORMATION FOR THE USER**

Opticrom[®] Allergy 2% w/v Eye Drops

sodium cromoglicate

SANOFI 

 Is this leaflet hard to see or read?
Phone 0845 372 7101 for help

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to use Opticrom Allergy carefully to get the best results from it.

- Keep this leaflet. You may need to read it again
- Ask your pharmacist if you need more information or advice
- You must contact a doctor if your symptoms worsen or do not improve
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

In this leaflet:

1. What Opticrom Allergy is and what it is used for
2. Before you use Opticrom Allergy
3. How to use Opticrom Allergy
4. Possible side effects
5. How to store Opticrom Allergy
6. Further information

1. What Opticrom Allergy is and what it is used for



Opticrom Allergy 2% w/v Eye Drops (called Opticrom Allergy in this leaflet) contain a medicine called sodium cromoglicate. This 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.

Opticrom Allergy 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

2. Before you use Opticrom Allergy



Do not use this medicine and tell your doctor or pharmacist if:

✕ You are allergic (hypersensitive) to sodium cromoglicate, or any of the other ingredients of Opticrom Allergy (listed in Section 6: Further information)

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 Opticrom Allergy.



Take special care with Opticrom Allergy 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 Opticrom Allergy.

Pregnancy and breast-feeding

Talk to your doctor before using this medicine if you are pregnant, might become pregnant or think you may be pregnant.

If you are breast-feeding or planning to breast-feed, talk to your doctor or pharmacist before taking or using any 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.

Important information about some of the ingredients of Opticrom Allergy

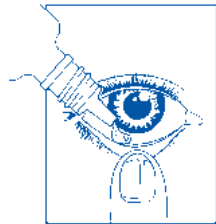
Opticrom Allergy contains benzalkonium chloride. This may cause your eyes to become irritated. It may also change the colour of your contact lenses.

3. How to use Opticrom Allergy

Always use Opticrom Allergy exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure

How to use this medicine

- Wash your hands
- 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 Opticrom Allergy 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 Opticrom Allergy

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 Opticrom Allergy

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. Opticrom Allergy 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 product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Opticrom Allergy can cause side effects, although not everybody gets them.

Stop using Opticrom Allergy and see a doctor as soon as possible if:

- The itching, redness or swelling gets worse. You may be allergic to these drops.

Talk to your doctor or pharmacist if any of the side effects gets serious or lasts 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.

United Kingdom

You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

Malta

ADR Reporting, The Medicines Authority, Post-Licensing Directorate, 203 Level 3, Rue D'Argens, GŻR-1368 Gżira

Website: www.medicinesauthority.gov.mt

e-mail: postlicensing.medicinesauthority@gov.mt

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Opticrom Allergy

Keep this medicine in a safe place where children cannot see or reach it.

Do not use Opticrom Allergy after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.

Store below 30°C. Keep the bottle in the outer carton in order to protect from light.

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

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Opticrom Allergy contains

- The solution contains 2.0% w/v of the active substance, sodium cromoglicate
- The other ingredients are disodium edetate, benzalkonium chloride and purified water

What Opticrom Allergy looks like and contents of the pack

Opticrom Allergy is a clear colourless to pale yellow solution supplied in a 5ml or 10 ml plastic dropper bottle with a tamper-proof cap



Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.