



PACKAGE LEAFLET: INFORMATION FOR THE USER

Opticrom[®] Allergy

2% w/v Eye Drops, Solution
sodium cromoglicate

SANOFI

Is this leaflet hard to see or read?

Phone +353 1 4035600 for help

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

This medicine is available without prescription. Always use this medicine exactly as described in this leaflet or as your 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 pharmacist or doctor. This includes any side effects not listed in this leaflet. See section 4.

- You must talk to a doctor if do not feel better or if you feel worse.

What is in this leaflet:

1. What Opticrom Allergy is and what it is used for
2. What you need to know before you use Opticrom Allergy
3. How to use Opticrom Allergy
4. Possible side effects
5. How to store Opticrom Allergy
6. Contents of the pack and other 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 relief and treatment of eye allergies. This includes:

- Short and long term allergic conjunctivitis (inflammation of parts of the eye)

- More severe cases of conjunctivitis ('vernal kerato conjunctivitis'). Signs include bumps inside the upper eyelid, sensitivity to light and severe itching

2. What you need to know before you use Opticrom Allergy

Do not use Opticrom Allergy if:

- You are allergic (hypersensitive) to sodium cromoglicate, or any of the other ingredients of Opticrom Allergy (listed in Section 6: Contents of the pack and other 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

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.
Using Opticrom Allergy may cause eye irritation. If this happens, do not drive or use any tools or machines.

Important information about some of the ingredients of Opticrom Allergy

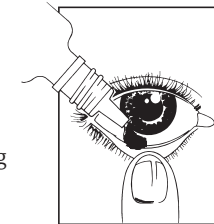
Opticrom Allergy contains benzalkonium chloride. This may cause your eyes to become irritated. It may also change the colour of your contact lenses. In order to avoid contact with soft contact lenses, remove contact lenses prior to application and wait at least 15 minutes before reinsertion.

3. How to use Opticrom Allergy

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
- 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 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

You should keep using these drops if you are still around the things that you are allergic to. If you stop using Opticrom Allergy, 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

Turn over

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 HPRA Pharmacovigilance, Website: www.hpra.ie.

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 out of the sight and reach of children.

Do not use Opticrom Allergy 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. Do not store above 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 discard any remaining contents four weeks after first opening the bottle. Avoid contamination of the contents by replacing the cap securely after use.

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 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 water for injection

What Opticrom Allergy looks like and contents of the pack

Opticrom Allergy is a clear colourless to pale yellow eye drops, solution supplied in a 5ml or 10ml plastic dropper bottle with a tamperproof cap. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Opella Healthcare France SAS, T/A Sanofi,
82 Avenue Raspail,
94250 Gentilly, France.
Tel: +353 1 4035600
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Manufacturer

Zentiva k.s., U Kabelovny 130,
102 37 Prague, Czech Republic

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

This leaflet was last revised in:
September 2021.

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GENERAL INFO:

PM CODE:	66455 (1060033984)
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CREATION DATE:	02.07.2021
AW BY:	LN
SUPPLIER:	N/A

REASON OF REVISION:

CHLOE_PCP, NO QP RELEASE OF BATCHES WITH THIS ARTWORK BEFORE 29 OCTOBER 2021, Opticrom Allergy 2% Eye Drops Ireland, Marketing Authorisation Transfer from Sanofi-aventis Ireland Ltd. (trading as Sanofi) to Opella Healthcare France SAS (trading as Sanofi). Changes required to the bottle label, carton label and the patient information leaflet. Proposed MAT submission date is 01 September 2021. Expected MAT approval date is 29 October 2021 (CHLOE DATE). Compliance Date = MAT approval date which is 29 October 2021. NO QP RELEASE OF BATCHES WITH THIS ARTWORK BEFORE 29 OCTOBER 2021. IMPORTANT NOTES REGARDING COMPLIANCE DATE. The compliance date refers to the QP batch release date of the product. Any batches released on or after the 29 October 2021 MUST use the amended packaging in this folder which cites the new PA number (PA23180/010/002). Any batches QP released BEFORE 29 October 2021 cannot be released with this packaging. All batches QP released BEFORE 29 October 2021 must use packaging with the old PA number (PA0540/116/002). CHLOE_PCP_4 : Changes linked to Chloe PCP

TECHNICAL INFO:

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COLOURS: [1]

■ Black

TECH. COLOURS: [1]

■ DieCut