

**PACKAGE LEAFLET:
INFORMATION FOR THE USER**

Opticrom[®]

Aqueous 2% w/v Eye Drops, Solution sodium cromoglicate

SANOFI 

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

Read all of this leaflet carefully before you start using this medicine

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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 Aqueous is and what it is used for
2. Before you use Opticrom Aqueous
3. How to use Opticrom Aqueous
4. Possible side effects
5. How to store Opticrom Aqueous
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1. What Opticrom Aqueous is and what it is used for 

Opticrom Aqueous 2% Eye Drops, Solution (called Opticrom Aqueous in this leaflet) contains 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 Aqueous is used for the prevention, 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. Before you use Opticrom Aqueous

 **Do not use this medicine and tell your doctor if:**

✕ You are allergic (hypersensitive) to sodium cromoglicate, or any of the other ingredients of Opticrom Aqueous (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 Aqueous.

 **Take special care with Opticrom Aqueous 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 Aqueous.

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 Aqueous

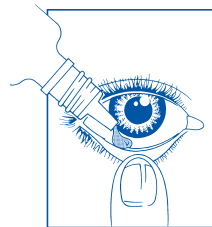
Opticrom Aqueous contains benzalkonium chloride. This may cause your eyes to become irritated. It may also change the colour of your contact lenses.

3. How to use Opticrom Aqueous

Always use Opticrom Aqueous exactly as your doctor 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 (adults, elderly and children)

- One or two drops in each eye four times a day, or as directed by your doctor
- If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor

If you use more Opticrom than you should

Talk to your doctor or go to a hospital straight away. Remember to take any medicine that is left with you so the doctor knows what you have taken.

**If you forget to use Opticrom Aqueous**

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 Aqueous

Keep using the eye drops until your doctor tells you to stop. Do not stop using the eye drops just because your eyes feel better.



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 Aqueous can cause side effects, although not everybody gets them.

Stop using Opticrom Aqueous 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 Aqueous

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

Do not use Opticrom Aqueous after the expiry date which is stated on the bottle 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 Aqueous 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 Aqueous contains**

- The solution contains 2% w/v of the active substance, sodium cromoglicate
- The other ingredients are disodium edetate, benzalkonium chloride and purified water

What Opticrom Aqueous looks like and contents of the pack

Opticrom Aqueous is a clear colourless to pale yellow solution supplied in a 13.5 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.

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