

Front Side

(Pharmacode Direction)

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PACKAGE LEAFLET: INFORMATION FOR THE USER

Opticrom Aqueous 2% w/v Eye Drops, solution

Sodium cromoglicate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

What is in this leaflet:

- What this medicine is and what it is used for
- What you need to know before you use this medicine
- How to use this medicine
- Possible side effects
- How to store this medicine
- 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.

This medicine 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 keratoconjunctivitis'). Signs include bumps inside the upper eyelid, sensitivity to light and severe itching.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE THIS MEDICINE

Do not use this medicine:

- If you are allergic (hypersensitive) 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.

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

Talk to your doctor or pharmacist before using this medicine

- If you wear soft contact lenses. You should not wear contact lenses while using these drops.

Other medicines and Opticrom Aqueous 2% w/v Eye Drops, solution

Tell your doctor or pharmacist if you are taking, have recently taken or might take 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

Sodium cromoglicate 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 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.
- 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.

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, ask your doctor.

If you use more of this medicine than you should

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

If this medicine is accidentally swallowed, talk to your doctor or pharmacist.

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 stop using this medicine

Keep using these 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, 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 ([www.mhra.gov.uk/yellowcard](http://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.



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5. HOW TO STORE THIS MEDICINE

Keep this medicine 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 medicine 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. 1ml of eye drops contains 20mg 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

Opticrom Aqueous 2% w/v Eye Drops is a clear colourless to pale yellow solution supplied in either a 5ml, 10ml or 13.5ml 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

Distributor

Thornton & Ross Ltd.  
Linthwaite  
Huddersfield  
HD7 5QH  
United Kingdom

Manufacturer

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

This leaflet was last revised in 08/2023

Produkt/Product : <b>OPTICROM AQU 2_ EDR 13.5ML TR GB_PIL</b>	
STADA Mat.-Nr./Mat.-No.: <b>9353356_2307 GB</b>	
STADA Art.-Nr./Art.-No: <b>N/A</b>	
Hersteller/Manufacturer: <b>Rafarm S.A.</b>	
Hersteller Art.-Nr./Manufacturer Art.-No.: <b>N/A</b>	
Format/Size: <b>135 x 550 mm</b>	
Schriftgröße/Font-size: <b>10pt - 16pt</b>	
NTIN/GTIN: <b>N/A</b>	
PZN/EAN: <b>N/A</b>	
Pharma-Code: <b>N/A</b>	
Flattermarke/Collating mark: <b>N/A</b>	
1. Farbe/Colour: <div></div> <b>Black</b>	
2. Farbe/Colour: <div></div> <b>Keyline (Non-Printing)</b>	
3. Farbe/Colour: <div></div> <b>Technical Info (Non-Printing)</b>	
4. Farbe/Colour:	
5. Farbe/Colour:	
6. Farbe/Colour:	
7. Farbe/Colour:	
8. Farbe/Colour:	
9. Farbe/Colour:	
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12. Farbe/Colour:	
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14. Farbe/Colour:	
15. Farbe/Colour:	
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Aktueller Umlauf/Current loop:	
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