



Opticrom®

Allergy Single Dose 2 % w/v
Eye Drops solution
sodium cromoglicate

sanofi

Package leaflet: Information for the user

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 a doctor if you do not feel better or if you feel worse.

What is in this leaflet

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

1. What Opticrom Single Dose is and what it is used for

Opticrom Allergy Single Dose 2 % w/v Eye Drops solution (called Opticrom Single Dose in this leaflet) contains a medicine called sodium cromoglicate. This belongs to a group of medicines called anti-allergics.

What Opticrom Single Dose is used for

Opticrom Single Dose is used to relieve and treat eye allergies in adults and children.

There are two types of eye allergy:

- 'perennial allergic conjunctivitis' – this can happen at any time of the year
- 'hay fever' or 'seasonal allergic conjunctivitis' – this happens in different seasons and is caused by different pollens.

Signs of allergies include itchy, watery, red or inflamed eyes and puffy eyelids.

How Opticrom Single Dose works

Opticrom Single Dose works by stopping the release of the natural substances in your eyes – these are the cause of the allergic reaction.

2. What you need to know before you use Opticrom Single Dose

Do not use Opticrom Single Dose:

- if you are allergic to sodium cromoglicate or any of the other ingredients of this medicine (listed in section 6). Signs include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue. Also, the redness, itching or swelling of the eyes or eyelids may get worse.

Do not use Opticrom Single Dose if the above applies to you.

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

Warnings and precautions

Once opened, use the single-dose container immediately. After use, throw away the container and any medicine left in it – do not use again. This is because the Opticrom Single Dose container is sterile and preservative-free.

If you wear contact lenses, follow the instruction for contact lens wearers in Section 3.

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 using this medicine.

Driving and using machines

You may have blurred eye-sight just after using this medicine. If this happens, do not drive or use any tools or machines until you can see clearly.

3. How to use Opticrom Single Dose

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 much to use

The recommended dose is:

- 1 or 2 drops in each eye
- 4 times a day.

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

Using this medicine

This medicine is for use in the eyes only (ocular use).

Do not swallow it.

- First wash your hands.
- Break off one single-dose container from the strip.
- Open the container by bending or twisting the tab – use it as soon as you have opened it.
- Tilt your head back.
- Pull down your lower eye lid.
- Squeeze 1 or 2 drops inside the eye lid – without touching your eye with the container.
- Close your eye.
- Wipe away any liquid from around the eye with a clean tissue. Then do the same to put the drops in the other eye.

After use, throw away the container and any medicine left in it – do not use again.

Contact lens wearers:

As with most topical eye medications, if you wear contact lenses, you should remove them before using Opticrom Single Dose.

After using this product, you should wait 15 minutes before putting your contact lenses back in.

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direction of travel

pack2edit

Digital - Packaging - Development

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File information

GMID code:	642072
Plant PM code:	10023835
Second Plant PM code:	65NOT6579/D
Version of artwork:	V1
PM type:	PI
Market:	IE
Format:	200 x 280 mm
Issue date of artwork:	12/May/2022
Print colors:	Black
Number of print colors:	1
Used font:	Agenda
Min. font size:	10 pt
p2e number:	931765-U05

Technical colors

Diecut-Legendcase	Free area	Glue points
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Additional Requirements of Packaging site

External dimensions:	200 x 280 mm
Size of folding leaflet:	200 x 46,66 mm (3 foldings after packing line)
Colors max :	2 colors
Bottle Pack :	4010/8-10-11



History

14/05/2014 : Addition of history

If you use more Opticrom Single Dose than you should
If you use the eye drops more often than you should, talk to your doctor or pharmacist.

If you forget to use Opticrom Single Dose

- 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 Single Dose

- If you stop using this medicine, your signs of allergies may come back. Opticrom Single Dose keeps your eye allergies from returning.
- Keep using the drops if you are still around the things that you are allergic to, even if your eye allergy has got better.

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 Opticrom Single Dose and talk to a doctor straight away if:

It is not known how often these happen.

- the itching, redness or swelling of your eyes gets worse – you may be allergic to these drops.

Other side effects can include:

It is not known how often these happen.

- mild eye irritation
- stinging or burning in your eyes or blurring of eye-sight – this should only last for a short time and happens immediately after using the eye drops.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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 Single Dose

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 label and carton after EXP. The expiry date refers to the last day of that month.

Store below 25°C.
Keep the single dose containers in the aluminium sachet in order to protect from light.

After opening the aluminum sachet, throw away any remaining contents after 28 days.
Once opened, use the single-dose container immediately. After use, throw away the container and any medicine left in it – do not use again. This is because the Opticrom Single Dose container is sterile and preservative-free.

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 Opticrom Single Dose contains

- The active substance is sodium cromoglicate. Each single dose container contains 20 mg/ml of sodium cromoglicate.
- The other ingredients are sodium chloride and purified water.

What Opticrom Single Dose looks like and contents of the pack

Opticrom Single Dose is a clear colourless to pale yellow solution supplied in single-dose container of 0.3 ml packaged in an aluminium sachet.

Pack sizes: 10 and 20 single-dose containers.
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.

Manufacturer
Laboratoire Unither
Espace Industriel Nord 151, rue André Durouchez CS 28028
80084 AMIENS
France

For any information about this medicine, please contact the distributor & local representative of the 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.

This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium: Alleophta unidose 20 mg/ml, oogdruppels, oplossing in verpakking voor éénmalig gebruik
Croatia: Alleofta 20 mg/ml kapi za oko, otopina u jednodoznom spremniku
Czech Republic: Alleophta 20 mg/ml
Ireland: Opticrom Allergy Single Dose 2% w/v Eye Drops, Solution
Italy: Sodiocromoglicato sanofi 20 mg/ml collirio monodose, soluzione
Luxembourg: Alleophta unidose 20 mg/ml, collyre en solution en récipient unidose
Poland: Alleoptical
Slovakia: Alleophta
Spain: Opticrom 20 mg/ml colirio en solución en envase unidosis
United Kingdom: Opticrom Allergy single-dose, 2% w/v Eye drops solution

This leaflet was last revised in April 2022.

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