Package leaflet: Information for the user

### SANOFI 🎝

## **Opticrom®** Allergy Single Dose 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.

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 contact your doctor if your symptoms worsen or do not improve.

### What is in this leaflet

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

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

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

### What Opticrom Allergy Single Dose is used for

- Opticrom Allergy 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 Allergy Single Dose works**

Opticrom Allergy 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 Allergy Single Dose

### Do not use Opticrom Allergy 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 Allergy 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 Allergy Single Dose container is sterile and preservative-free. If you wear contact lenses, follow the instruction for contact lens

wearers in section 3.

Talk to your doctor or pharmacist if you are not sure whether the child has allergic eyes. Also do this, if you have any other questions about using these eye drops in a child.

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 vou can see clearly.

### 3. How to use Opticrom Allergy 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 contact your doctor if your symptoms worsen or do not improve.

### 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 vour 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 Allergy Single Dose. After using this medicine, you should wait 15 minutes before putting your contact lenses back in.

### If you use more Opticrom Allergy 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 Allergy 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.

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| GMID code:              | 620799         |  |  |  |  |  |  |
| Plant PM code:          | 10015052       |  |  |  |  |  |  |
| Second Plant PM code:   | 65NOT6547/D    |  |  |  |  |  |  |
| Version of artwork:     | V1             |  |  |  |  |  |  |
| PM type:                | PI             |  |  |  |  |  |  |
| Market:                 | GB             |  |  |  |  |  |  |
| Format:                 | 200 x 280 mm   |  |  |  |  |  |  |
| Issue date of artwork:  | 08/Jul/2021    |  |  |  |  |  |  |
| Print colors:           | Black          |  |  |  |  |  |  |
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|                         |                |  |  |  |  |  |  |
| Number of print colors: | 1              |  |  |  |  |  |  |
| Used font:              | Ocean Sans Pro |  |  |  |  |  |  |
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| Technical colors  |           |             |  |
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| Diecut-Legendcase | Free area | Glue points |  |

| Additional Require       |  |         |
|--------------------------|--|---------|
| External dimensions:     | 200 x 280 mm                                   | UNITHER |
| 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 |  |  |  |
|                                  |  |  |  |
|                                  |  |  |  |
|                                  |  |  |  |

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### If you stop using Opticrom Allergy Single Dose

• If you stop using this medicine, your signs of allergies may come back. Opticrom Allergy 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 Allergy 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 the Yellow Card Scheme at: 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.

### 5. How to store Opticrom Allergy 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 aluminium 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 Allergy 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 Allergy Single Dose contains

• The active substance is sodium cromoglicate. Each single-dose container contains 2% w/v of sodium cromoglicate.

• The other ingredients are sodium chloride and purified water.

### What Opticrom Allergy Single Dose looks like and contents of the pack

Opticrom Allergy 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 Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK. Tel: 0800 035 2525 e-mail: uk-medicalinformation@sanofi.com

### Manufacturer

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

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 07/2021



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