75mm

PACKAGE LEAFLET:
INFORMATION FOR THE USER

Opticrom® 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 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. 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.

What is in this leaflet

1. What Opticrom is and what it is used for

Opticrom 2% Eye Drops (called Opticrom 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 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

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 (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.

Take special care with Opticrom 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.

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.

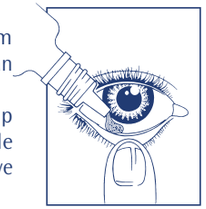
Driving and using machines
You may have blurred eyesight straight after using this medicine. If this happens, do not drive or use any tools or machines until you can see clearly.
Using Opticrom Eye drops may cause eye irriation. If this happens, do not drive or use any tools or machines.

Important information about some of the ingredients of Opticrom
Opticrom 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

Always use Opticrom 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 forget to use Opticrom
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
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 can cause side effects, although not everybody gets them.
Stop using Opticrom 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. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

Turn Over

75mm

5. How to store Opticrom

Keep this medicine out of the sight and reach of children.
Do not use Opticrom 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 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 to protect the environment.

6. Contents of the pack and other information

What Opticrom 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 looks like and contents of the pack

Opticrom is a clear colourless to pale yellow solution supplied in a 13.5 ml 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
email: IEmedinfo@sanofi.com

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 revised in September 2021.

1060033985
ZV/664 54

ZENTIVA

GENERAL INFO:

PM CODE:	66454 (1060033985)
PRODUCT NAME:	OPTICROM 200MG/10ML EYDRO BT1 RX M18 IE
SAP ID / GMID:	11009513 / 730715
AW VERSION:	V2
CREATION DATE:	02.07.2021
AW BY:	LN
SUPPLIER:	N/A

REASON FOR CHANGE:

CHLOE_PCP - NO QP RELEASE OF BATCHES WITH THIS ARTWORK BEFORE 29 OCTOBER 2021. Opticrom 2% Eye Drops. 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. The artwork was approved "at risk" as agreed with Head of Regulatory Affairs Consumer Healthcare UK & Ireland (see attached signed statement). 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 (PA23180/010/001). 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 (PA0540/116/001) CHLOE_PCP_4 : Changes linked to Chloe PCP

TECHNICAL INFO:

FORMAT (size):	140 x 360 mm
LAETUS (pharma code):	(312) 00110100; L - 3, C - 2, R - 2
FONT + MIN. SIZE:	Ocean Sans Pro 9 pt
MATERIAL TYPE (TS):	PRG - see TS in eDMS

COLOURS: [2]

- Black
- Pantone Reex Blue

TECH. COLOURS: [1]

- DieCut