

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed without a doctor's prescription

Opticrom Eye Drops

SANOFI 

The active ingredient and its concentration:

Sodium cromoglycate 2.0% w/v.

Inactive ingredients - see section 6.

Read this leaflet carefully in its entirety before using the medicine.

This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist. This medicine is administered without need for a doctor's prescription. Use it properly. Consult a pharmacist if you need further information. Refer to the doctor if the signs of the ailment (symptoms) worsen or if they do not improve after two days. Keep this leaflet. You may need to read it again. If any side effect worsens or if a side effect not mentioned in this leaflet occurs, please refer to the doctor or pharmacist.

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended as a preventive treatment for all types of allergic conjunctivitis.

Therapeutic group: The active ingredient belongs to the group of antiallergics.

2. BEFORE USING THE MEDICINE:

Do not use this medicine and tell your doctor or pharmacist if:

You have a known sensitivity to the active ingredient of the medicine (sodium cromoglycate), or to the ingredients of the medicine (see section 6). Signs of an allergic reaction include: rash, swallowing or breathing problems, swelling of the lips, face, throat, tongue and worsening of the redness, itch or swelling of the eye or eyelid.

Special warnings regarding use of the medicine

Before commencing treatment, be sure that the irritation in your eyes is a result of allergy. If you are not sure, refer to a doctor before commencing treatment.

Do not wear soft contact lenses during the course of treatment with Opticrom Eye Drops.

If you are uncertain, consult a doctor or pharmacist before commencing treatment with Opticrom Eye Drops.

Pregnancy and breastfeeding

If you are pregnant, might become pregnant or think you may be pregnant, or if you are breastfeeding or are planning to breastfeed, do not use the medicine without consulting a doctor before commencing treatment.

Driving and use of machinery

Blurred vision and local irritation in the eye may occur immediately after use of the medicine. In this case, do not drive or operate dangerous machines until vision clears.

Important information regarding some of the ingredients of the medicine

Opticrom Eye Drops contain benzalkonium chloride. This reagent may cause irritation of the eyes and to a change in the color of contact lenses.

3. HOW SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you are uncertain.

The usual dosage is generally: 1-2 drops in each eye, 4 times a day at regular intervals or as instructed by the doctor.

Use Opticrom Eye Drops regularly to ensure optimal treatment of the symptoms of the allergic inflammation.

Do not exceed the recommended dose.

Do not swallow. For external use only.

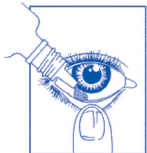
Directions for use – general instructions:

a. In order to prevent contamination, do not allow the tip of the bottle to touch any surface (including the eye itself). Keep the bottle closed tightly.

b. The bottle of drops may not be full; this is to allow better control of the drip rate.

c. How to use the drops:

1. Wash your hands thoroughly.
2. Use a mirror that will help you see your actions.
3. Carefully dry your eyes with a tissue and remove the cover of the bottle.
4. With the help of your finger, slightly pull the lower eyelid away from the eye. Carefully instill 1-2 drops into the gap that has formed. Take care not to allow the tip of the bottle to come into contact with the eye.
5. Release the lower eyelid and blink a few times to ensure full distribution of the liquid in the eye.
6. Repeat steps 4 and 5 in the second eye, if necessary.
7. To prevent contamination of the solution, be sure that the tip of the bottle does not come into contact with any surface, including the finger or eye, and close the bottle tightly.



d. After using the medicine, wash your hands thoroughly to clean them of any remnants of the medicine.

e. To prevent spread of the infection, do not use the same bottle of medicine for more than one person.

Duration of treatment:

If the eye condition worsens or does not improve after 2 days of use of the eye drops, please refer to the doctor or pharmacist.

Do not use Opticrom Eye Drops for more than three consecutive months without consulting with a doctor.

If the medicine is taken under a doctor's instructions, complete the treatment regimen he has recommended.

Do not use the preparation for more than 4 weeks after opening the bottle.

If you used more Opticrom Eye Drops than necessary:

Refer to the doctor if you used the eye drops more frequently than recommended or for more than three months.

If a child accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of this medicine with you.

If you forgot to take this medicine at the scheduled time, use the drops as soon as you remember. But, if the time you remembered is close to the time you are to take the next dose, skip the forgotten dose. Do not take a double dose to compensate for a missed dose.

If you stop taking the medicine:

Even if there is an improvement in the signs of the disease, continue using these drops if you are still around the factors to which you are allergic. Opticrom Eye Drops may prevent an allergic reaction, so if you stop the treatment, the signs of the allergy may recur.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult a doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Opticrom Eye Drops may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Discontinue treatment with the medicine and refer to the doctor as soon as possible if: the stinging, redness or swelling worsen. You may be allergic to the preparation.

Consult the doctor or pharmacist if the following side effects worsen or persist for more than a few days, or if you notice any side effects not mentioned in this leaflet:

- Stinging and burning in the eyes or blurred vision. These effects may persist for a short time only and occur immediately after using the drops.
- Mild irritation in the eye.

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach of children and/or infants to avoid poisoning.

Do not induce vomiting without explicit instruction from the doctor.

Do not use the medicine after the expiry date (exp. date) that appears on the package.

The expiry date refers to the last day of that month.

Store at a temperature below 30°C.

Store in the original package to protect from light.

Do not use the preparation for more than 4 weeks after first opening the bottle.

Do not store different medicines in the same package.

6. FURTHER INFORMATION

- In addition to the active ingredient, the medicine also contains: Benzalkonium chloride, disodium edetate, water for injection.
- What does the medicine look like and what are the contents of the package: a clear, colorless or very light yellow liquid in a small bottle with a dropper.
- License holder and address: sanofi-aventis Israel, Ltd., P.O.B. 8090, Netanya 4250499.
- Manufacturer and address: Sanofi Winthrop Industries, France.
- This leaflet was checked and approved by the Ministry of Health in July 2013.
- This leaflet does not contain all the information about your medicine. If you have any questions or if are not sure about anything, please ask your doctor.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 344922468.