

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

This medicine is dispensed without a doctor's prescription.

CROMOPTIC, Eye Drops

The active ingredient and its concentration:

Sodium cromoglycate 2.0% w/v

For a list of the inactive ingredients, please see Section 6 – "Additional information".

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

This leaflet contains concise information about the medicine. If you have any further questions, refer to your doctor or pharmacist. You must use the medicine correctly. Consult your pharmacist if you need additional information. You should consult your doctor if your symptoms worsen or do not improve after two days.

Keep this leaflet. You may need to read it again.

1. What is this medicine intended for?

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

Therapeutic group: The active ingredient belongs to the anti-allergy group of medicines.

2. Before using this medicine

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

- There is a known sensitivity to the medicine's active ingredient (sodium cromoglycate) or to any of the medicine's other ingredients (see Section 6). Signs of an allergic reaction include: rash, difficulty swallowing or breathing, swelling of the lips, face, throat, or tongue, and a worsening in the redness, itchiness or swelling of the eye or eyelid.

Special warnings regarding the use of this medicine:

Before starting the treatment you must be certain that the irritation in your eyes is the result of an allergy. If you are uncertain, you should consult your doctor before starting treatment.

If you are taking or have recently taken other medicines, including non-prescription medicines and dietary supplements, inform the doctor or pharmacist. This is especially important if you are taking other medicines used in the eyes.

Pregnancy and breastfeeding:

Do not use this medicine without first consulting a physician if you are pregnant, might become pregnant, or think you may be pregnant, or if you are breastfeeding or planning to breastfeed.

Driving and using machines:

Your vision may be blurred immediately after using the medicine. In that case, do not drive or operate dangerous machinery until your vision clears.

Important information regarding some of the ingredients of this medicine:

Cromoptic contains thiomersal. This substance can cause an allergic reaction in the eye.

3. How should this medicine be used?

If you are unsure how to use the medicine, consult the doctor or pharmacist.

The usual dosage is: 1-2 drops in each eye, 4 times a day at set intervals, or according to your doctor's instructions.

Do not exceed the recommended dose.

Do not swallow. For external use only.

How to use the product – general instructions:

- A. In order to avoid contamination, do not allow the tip of the bottle to touch any surface (including the eye itself). Keep the bottle tightly closed.
- B. The bottle of drops may not be full; this is meant to enable better control over the rate at which the drops fall.
- C. How to use the drops:
 1. Wash your hands thoroughly.
 2. Use a mirror to help you see what you are doing.
 3. Carefully dry your eyes using a tissue, and remove the cap from the bottle.
 4. Using a finger, pull your lower eyelid slightly away from the eye, forming a pocket. Carefully instill 1-2 drops into the pocket. Make sure that the tip of the bottle does not come into contact with the eye.
 5. Release the lower eyelid and blink several times to ensure the liquid is fully distributed over the eye.
 6. Make sure to close the cap of the bottle immediately after use.
 7. Repeat steps 4 and 5 in the other eye as well, if necessary.

The duration of treatment:

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

Do not use Cromoptic for more than three consecutive months without consulting your doctor.

If the medicine is being taken according to a doctor's instructions, you should complete the treatment as recommended by the doctor.

Do not use the product more than one month after opening the bottle.

If you have used more Cromoptic than you should have:

Refer to a doctor if you have used the eye drops more often than recommended or for a period of time longer than three months.

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

If you forgot to take the medicine at the appropriate time, use the drops as soon as you remember. However, if you remember at a time near that of the next dose, skip the dose you missed. Do not take a double dose to make up for the forgotten dose.

If you wish to stop taking this medicine, please note:

Even if your symptoms have improved, you must continue to use these drops if you are still in an environment containing the substances to which you are allergic. Cromoptic may prevent an allergic reaction, so if you stop the treatment, the allergy symptoms may return.

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 the use of this medicine, consult your doctor or pharmacist.

4. Side effects:

As with any medicine, the use of Cromoptic may cause side effects in some users. Do not be alarmed by the list of side effects. You may not experience any of them.

Stop using the medicine and refer immediately to a doctor if: the stinging, redness or swelling worsens. You may be allergic to the product.

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

- Stinging and burning in the eyes, or blurred vision. These side effects should only last a short time and should appear immediately after using the drops.
- Mild irritation of the eye.
- Side effects can be reported to the Ministry of Health by clicking the link "Report of side effects due to medication" on the home page of the Ministry of Health website (www.health.gov.il), which will open an online form for reporting side effects, or by directly accessing: <https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdverseEffectMedic@moh.gov.il>

5. How should the medicine be stored?

Avoid poisoning! This medicine, and all other medicines, must be stored in a closed place out of the reach of children and/or infants, to prevent poisoning.

Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use this medicine after the expiry date indicated on the package. The expiry date refers to the last day of that month.

Store at a temperature below 25°C.

Store in the original package to protect the product from light.

Do not use this medicine for more than 30 days after the bottle is first opened.

Do not store different medicines in the same package.

6. Additional information

In addition to the active ingredient, this medicine also contains:

Sodium chloride, thiomersal, sodium hydroxide, disodium edetate, purified water.

What the medicine looks like and what the package contains:

A clear, colorless to yellowish liquid in a bottle with a dropper.

Manufacturer: Vitamed Pharmaceutical Industries Ltd.
P.O.B. 114, Binyamina 3055002, Israel.

This leaflet was reviewed and approved by the Ministry of Health in:
November 2016

This leaflet does not contain all of the information regarding this product. If you have any questions or if you are unsure of anything, please refer to your doctor.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 100352857