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1.5.3 Patient Information Leaflet (PIL)

Package leaflet: Information for the patient

CROMSOL eye drops solution 2% Sodium cromoglicate

Read all of this leaflet carefully before you start using this medicine.

This medicine is available without prescription. However, you still need to use CROMSOL carefully to get the best results from it

- . Keep this leaflet. You may need to read it again.
- . If you have any further questions, ask your doctor or pharmacist.
- . You must contact a doctor if your symptoms worsen or do not improve.
- . If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist (see section 4).

In this leaflet:

1. WHAT CROMSOL IS AND CONTENT OF THE PACK
2. WHAT YOU NEED TO KNOW BEFORE YOU USE CROMSOL
3. HOW TO USE CROMSOL
4. POSSIBLE SIDE EFFECTS
5. HOW TO STORE CROMSOL
6. CONTENT OF THE PACK AND OTHER INFORMATION

1. WHAT CROMSOL IS AND WHAT IT IS USED FOR

CROMSOL eye drops contain a medicine called sodium cromoglicate (cromolyn) an active substance belonging to anti-allergics.

CROMSOL is used for the preventive treatment of eye allergies (more specifically, pollen conjunctivitis, seasonal conjunctivitis and marginal keratoconjunctivitis) that are recognisable from swollen eyes or eyelids, red eyes and stinging or watery eyes.

You must refer to your doctor if you feel no improvement or if you feel worse.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE CROMSOL

Do not use CROMSOL:

- if you are allergic (hypersensitive) to sodium cromoglicate or any of the other ingredients of CROMSOL, listed in section 6.

Warnings and precautions:

- if your condition does not improve or if your symptoms persist, consult your doctor.
- if you wear soft contact lenses you should not use CROMSOL because it contains a preservative agent (benzalkonium).

Other medicines and CROMSOL

If you use other eye drops in solution, respect a **15 minutes interval** between instillations.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

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Use of CROMSOL only after medical advice. 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 taking this medicine.

Driving and using machines

You may have feel a transient visual disturbance after using CROMSOL. It is recommended to wait until symptoms disappear before driving a vehicle or using machines.

3. HOW TO USE CROMSOL

Always use CROMSOL exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose in adults and children is one or two drops in each eye 4 times a day. If there is no improvement or if your symptoms persist, consult your doctor.

This medicine is only for ophthalmic use.

1. wash your hands prior to instillation.
2. avoid touching your eye or eyelid with the tip of the bottle.
3. squeeze one drop inside the lower lid while looking upwards.
4. put the cap back on the bottle after use.

CROMSOL should be continuously used as long as you are exposed to the allergic source, otherwise your symptoms may reappear.

If you forget to use CROMSOL:

Do not use a double dose to make up for a forgotten dose Continue your treatment as planned.

If you use more CROMSOL than you should:

In such cases please contact your doctor or pharmacist.

There are no known effects of using too much of this medicine.

In case of overdose, medical observation should be sufficient.

If you stop using CROMSOL

If you stop the treatment, the symptoms might reappear if you are still exposed to the factors in charge of eye allergy.

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.

The following effects can occur at the level of the eye

- Allergic reaction to any component of the medicine.
- Transient visual troubles (stinging, burning).
- Transient vision trouble just after use of the 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 national reporting system.

5. HOW TO STORE CROMSOL

Keep out of the sight and reach of children.

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Do not use CROMSOL after the expiry date which is stated on the carton. Do not store above 30° C. Keep the bottle in the outer pack in order to protect from light. Do not use the eye drops for more than 4 weeks after first opening.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENT OF THE PACK AND OTHER INFORMATION

What CROMSOL contain

The active substance is sodium cromoglicate (cromolyn) at a concentration of 20 mg/ml. The other ingredients are: sodium chloride, edetate disodium, benzalkonium chloride, polysorbate 80 and water for injections.

What CROMSOL looks like and contents of the pack

CROMSOL eye drops is available in bottle containing 5 ml of clear solution.

This leaflet was last updated in 01/2019

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Zoning Industriel de Nivelles Sud, Zone 2

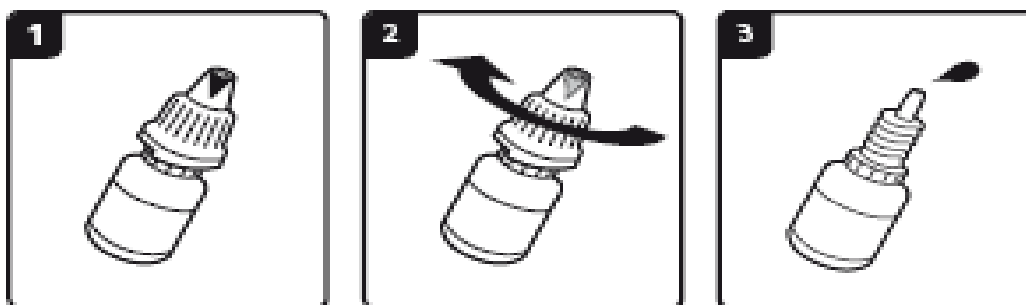
Av. Thomas Edison 105 - 1402 Thines

Belgium

Phone 32 (0)67 68 84 05

Fax 32 (0)67 68 84 19

Manufacturer: Ahlcon Parenterals (I) SP-917-918, Phase-III, Ind. Area, Bhiwadi-301019, Dist. Alwar (Rajasthan)



1. With the spike: tighten the cap on the nozzle
2. The spike in the cap will pierce the tip of the bottle
3. Dispense drops with gentle pressure. Replace the cap after every use.