

Package leaflet: Information for the patient

Sodium cromoglicate 2% w/v eye drops

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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

What is in this leaflet

1. What Sodium Cromoglicate is and what is it used for
2. What you need to know before you use Sodium Cromoglicate
3. How to use Sodium Cromoglicate
4. Possible side effects
5. How to store Sodium Cromoglicate
6. Contents of the pack and other information

1. What Sodium Cromoglicate is and what is it used for

The active ingredient Sodium Cromoglicate belongs to a group of medicines called anti-inflammatory/anti-allergy agents. Sodium Cromoglicate Eye Drops are used to treat red, watery, itchy eyes caused by allergies such as hayfever, house dust mites and pet hair.

2. What you need to know before you use Sodium Cromoglicate

Do not use Sodium Cromoglicate

- If you are allergic (hypersensitive) to Sodium Cromoglicate or any of the other ingredients of this medicine (listed in section 6)

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 these eye drops.

Warning and Precautions

Talk to your doctor or pharmacist before using this medicine

- If you wear soft contact lenses. You should not wear contact lenses while using these eye drops.

Other medicines and Sodium Cromoglicate

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

Pregnancy and breast-feeding

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 blurred eyesight straight after using this medicine. If this happens, do not drive or use any tools or machines until you can see clearly.

Sodium Cromoglicate Eye Drops contains benzalkonium chloride:

This medicine contains 0.10 mg /ml benzalkonium chloride as preservative. Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards.

Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

3. How to use Sodium Cromoglicate

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

The recommended dose is one or two drops in each eye four times daily or as directed by your doctor.

If you are using in combination with another eye drop medicine, wait 5-15 minutes before applying the second eye drop.

If your symptoms do not improve within 2 days, or if you need to use these drops for more than 3 months, you should consult your doctor.

Instructions for use:

(Please also refer to pictograms at the end of the leaflet)

- First wash your hands
- Avoid touching the eye (or any other surface) with the tip of the bottle
- If you wear soft contact lenses, they should be removed before using the eye drops and wait at least 15 minutes before reinserting
- These drops are supplied as a sealed bottle with a spiked cap. When using the bottle for the first time, screw the cap down tightly in order to pierce the tip of the bottle
- Tilt your head back and look at the ceiling
- Pull the lower eyelid gently downwards
- Hold the bottle upside down above the eye and gently squeeze the bottle to release a drop into your eye
- Keep the affected eye closed and press your fingertip against the inside corner of the closed eye, and hold for 1 minute
- Repeat for the other eye if necessary
- Replace and tighten the cap immediately after use.

Be careful not to touch the tip of the bottle on your eye or on any other surface. Ocular solutions, if handled wrongly, can become contaminated by common bacteria and cause eye infections. If you do develop any other eye condition whilst using this product, see your doctor immediately.

If you use more Sodium Cromoglicate than you should

Talk to your doctor or pharmacist or go to the hospital straight away. Remember to take any medicine that is left with you, so the doctor knows what you have used.

If you forget to use Sodium Cromoglicate

Apply the drops as soon as you remember. However, if it is almost time for your next dose, do not double your dose and carry on with the normal schedule dose.

If you stop using Sodium Cromoglicate

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 medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Sodium Cromoglicate can cause side effects, although not everybody gets them. **All medicines can cause allergic reactions, although serious allergic reactions are very rare.**

Stop taking this medicine and see your doctor straight away if you get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash, or itching (especially affecting your whole body). You may be allergic to these drops.

Talk to your doctor or pharmacist if any of the side effects get serious or last 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 occur immediately after using the eye drops.
- eye irritation.

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 Sodium Cromoglicate

Keep this medicine out of the sight and reach of children.

Do not store at a temperature above 30°C.

Protect from direct sunlight

Discard the bottle 28 days after opening, even if there is solution remaining.

Do not use Sodium Cromoglicate after the expiry date which is stated on the bottle and on the carton the bottle is packed in. The expiry date refers to the last day of that month. Make sure the container is properly closed. 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. Content of the pack and other information

What Sodium Cromoglicate contains

The active ingredient is Sodium Cromoglicate 2% w/v. The eye drops also contain benzalkonium chloride (as preservative) 0.01% w/v, sodium chloride, disodium edetate, polysorbate 80 and water for injections.

What Sodium Cromoglicate looks like and contents of the pack

Each bottle contains 13.5ml of Sodium Cromoglicate Eye Drops. Your medicine is a clear colourless solution, free from visible particulate matter.

Marketing Authorisation Holder and Manufacturer

FDC International Ltd, Unit 6, Fulcrum 1, Solent Way, Whiteley, Fareham, Hampshire, PO15 7FE

United Kingdom

Tel: + 44 (0) 1489 565222

E-mail: fdcil@btconnect.com

PL number: 15872/0010 (13.5ml)

Hard to see or read the leaflet? Call + 44(0) 1489 565222 for help.

This leaflet was last revised in: October 2020

MODE OF USE



Tighten the cap on the nozzle till the cap touches the shoulder.



The spike in the cap will pierce the tip of the bottle.



Tilt head backwards. Dispense drops with gentle pressure. Do not touch dropper tip to the surface of the eye.