

PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

Sodium Cromoglicate 2% w/v Eye Drops, solution

Sodium cromoglicate

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 of the side effects, talk to your doctor or pharmacist.
This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

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

1. WHAT SODIUM CROMOGLICATE EYE DROPS IS AND WHAT IT IS USED FOR

Sodium Cromoglicate Eye drops contain sodium cromoglicate which 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.

Sodium Cromoglicate Eye drops is used for the prevention, 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 keratoconjunctivitis'). Signs include bumps inside the upper eyelid, sensitivity to light and severe itching.

2. BEFORE YOU USE SODIUM CROMOGLICATE EYE DROPS

Do not use Sodium Cromoglicate Eye Drops

- if you are allergic (hypersensitive) to sodium cromoglicate or any of the other ingredients of Sodium Cromoglicate Eye Drops (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.

Warnings 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 drops.

Using other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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

Sodium cromoglicate may interfere with your ability to drive and use 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.

This medicine contains benzalkonium chloride

Sodium Cromoglicate Eye drops contains 0.1 mg benzalkonium chloride in each ml of solution.

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 EYE DROPS

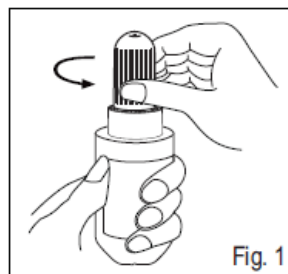
Always use Sodium Cromoglicate Eye Drops exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Opening the dropper container before first use

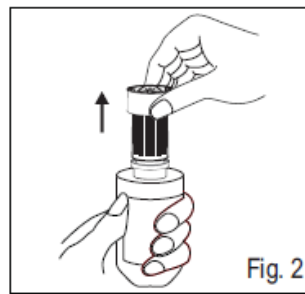
For Sodium Cromoglicate Eye Drops Containers of 5 ml and 10 ml:

Note: The dropper container should not be used if the tamper-proof base ring with cap is broken before you first use it.

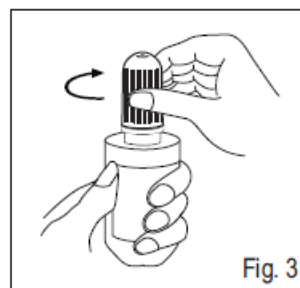
1. Turn the cap in counter clockwise direction. This will break the tamper-proof base ring (Fig.1).



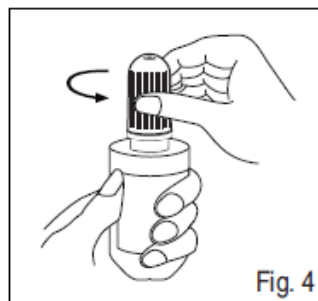
2. Remove the tamper-proof base ring by retaining the cap on the container (Fig.2).



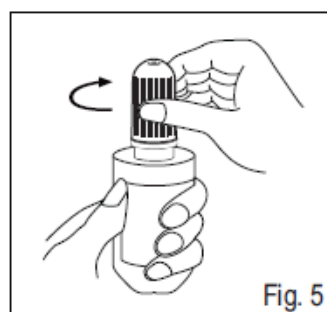
3. Tighten the cap on the nozzle so that the edge of the cap and the edge of bottle neck are totally aligned. Turning the screw cap clockwise will pierce the tip of the dropper container (Fig.3).



4. To open the dropper container, remove the cap by turning it in the counter clockwise direction (Fig.4).



5. Tighten the cap on the container after every use (Fig.5).

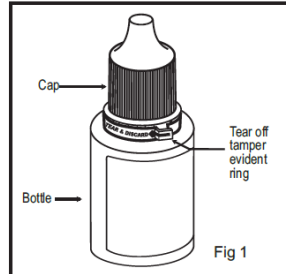


For Sodium Cromoglicate Eye Drops Containers of 15 ml (13.5 ml fill volume):

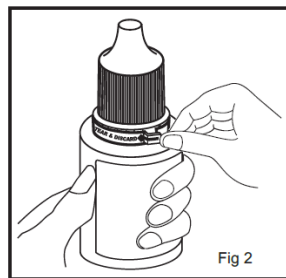
Note: You must not use the dropper container if the tamper-proof seal on the bottle neck is broken before you first use it.

Opening the dropper container before first use

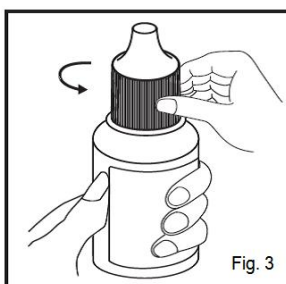
1. Before using the medicine for the first time, be sure the tamper evident ring between the dropper container and the cap is unbroken (Fig.1).



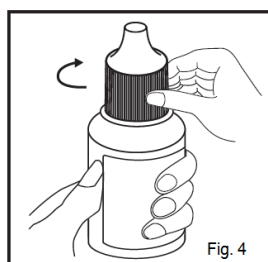
2. Before opening the dropper container for the first time, tear off the tamper evident ring to break the seal (Fig.2).



3. To open the dropper container, remove the cap by turning it in the counter clockwise direction (Fig.4).

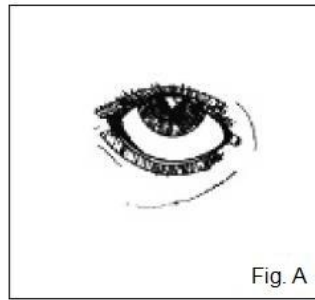


4. Tighten the cap on the container after every use (Fig.4).

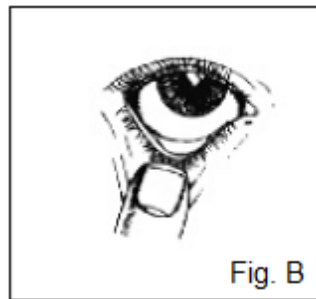


How to use this medicine

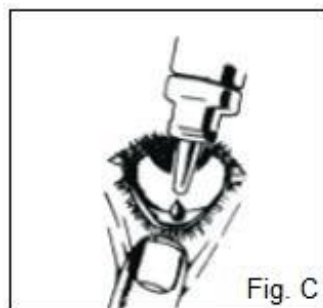
A. Wash your hands, tilt your head back and look at the ceiling (Fig.A).



B. Gently pull the lower eyelid down to form a small pocket between the eyelid and the eye (Fig. B).

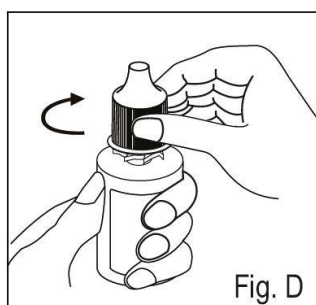


C. Turn the dropper container upside down and squeeze it gently to release one drop into each eye that needs treatment. Do not touch your eye or eyelid with the dropper tip (Fig. C). If a drop misses your eye, try again.



Close your eye after placing the drop(s) in your eye. Wipe away any excess liquid from the eyes with a clean tissue.

D. Reclose the dropper container after use (Fig.D). Repeat in the other eye if needed. The next time you need to apply the drops follow steps A-D



How much to use

- 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, ask your doctor.

If you use more of 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 this medicine is accidentally swallowed, talk to your doctor or pharmacist.

If you forget to use Sodium Cromoglicate Eye Drops

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 Sodium Cromoglicate Eye Drops

Keep using these 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, Sodium Cromoglicate Eye Drops can cause side effects, although not everybody gets them.

Stop using Sodium Cromoglicate Eye drops and see a doctor as soon as possible if:

- The itching, redness or swelling gets worse. You may be allergic to this medicine.

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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme at Website: 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 EYE DROPS

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

Do not use Sodium Cromoglicate Eye Drops after the expiry date which is stated on the bottle label and carton after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions before opening the bottle. After opening the bottle, "Do not store above 25°C". Sodium Cromoglicate Eye drops 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 protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Sodium Cromoglicate Eye Drops contains

- The active substance is sodium cromoglicate. Each 1ml of eye drops contains 20mg of sodium cromoglicate (2.0% w/v). One drop contains 0.7mg of sodium cromoglycate.
- The other ingredients are disodium edetate, benzalkonium chloride and water for injections.

What Sodium Cromoglicate Eye Drops looks like and contents of the pack

Sodium Cromoglicate Eye drops is a clear colourless to pale yellow solution supplied in either a 5 ml, 10 ml or 15 ml (13.5 ml fill volume) plastic dropper bottle with a white plastic screw cap having a tamper-proof base ring.

Marketing Authorisation Holder and Manufacturer

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This medicinal product is authorised in the Member States of the EEA under the following names:

UK: Sodium Cromoglicate 2% w/v Eye Drops, solution

This leaflet was last approved in 04/2023.