

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.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Sodium Cromoglicate Eye Drops is and what it is used for
2. 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. Further information

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

Sodium Cromoglicate Eye drops contain a medicine called sodium cromoglicate.

This 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 relief and treatment of eye allergies. These allergies can happen:

- At any time of the year and is called 'perennial allergic conjunctivitis'
- In different seasons of the year caused by different pollens.
This is called 'seasonal allergic conjunctivitis' or hay fever

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: Further information)

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.

Take special care with Sodium Cromoglicate Eye Drops if:

- You wear soft contact lenses. You should not wear contact lenses while using these drops
- If you are not sure if the above applies to you, talk to your doctor or pharmacist before using Sodium Cromoglicate Eye drops.

Using other medicines

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

Talk to your doctor before using this medicine if you are pregnant, might become pregnant or think you may be pregnant.

If you are breast-feeding or planning to breast-feed, talk to your doctor or pharmacist before taking or using any 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.

Important information about some of the ingredients of Sodium Cromoglicate Eye Drops

Sodium Cromoglicate Eye drops contains benzalkonium chloride. This may cause your eyes to become irritated and may change the colour of your contact lenses. Avoid contact with soft contact lenses. Remove contact lenses prior to application and wait at least 15 minutes before reinsertion.

3. HOW TO USE SODIUM CROMOGLICATE EYE DROPS

Always use Sodium Cromoglicate Eye Drops exactly as your doctor has told you.

Adults and Children over 6 years:

One or two drops to be administered into each eye four times daily.

Children under 6 years

Sodium Cromoglicate Eye drops should not be used in children under 6 years of age.

Elderly

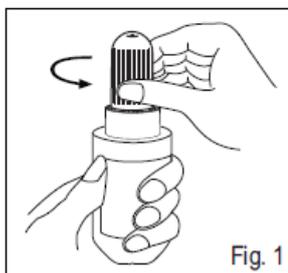
There is no evidence to suggest that a different dose is needed for elderly patients.

You should check with your doctor or pharmacist if you are not sure.

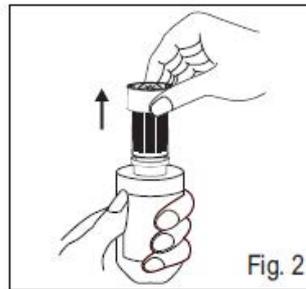
Opening the dropper container before first use

Note: Do not use the bottle if the tamper-proof base ring with cap is broken before you first use it.

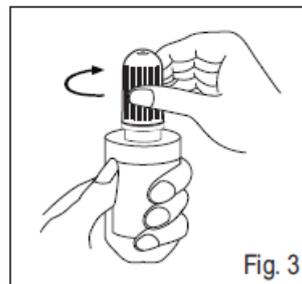
1. Turn the cap in counter clockwise direction. This will break the tamper-proof base ring (Fig.1).



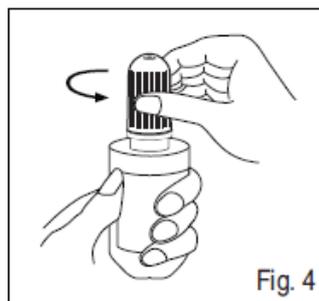
2. Remove the tamper-proof base ring by retaining the cap on the container (Fig.2).



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).

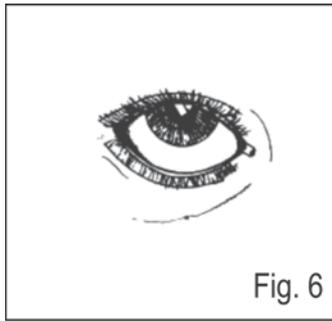


5. Tighten the cap on the container after every use (Fig.5).

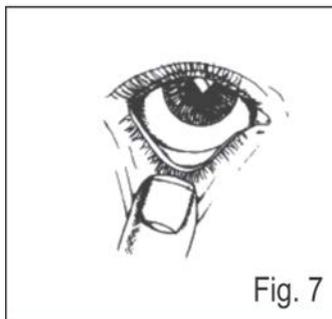


How to use this medicine

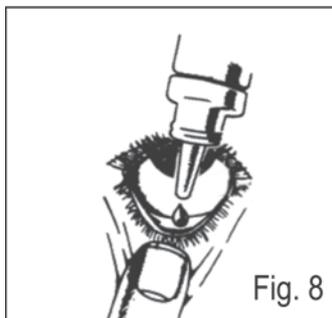
6. Wash your hands, tilt your head back and look at the ceiling (Fig.6).



7. Gently pull the lower eyelid down to form a small pocket between the eyelid and the eye. (Fig. 7).

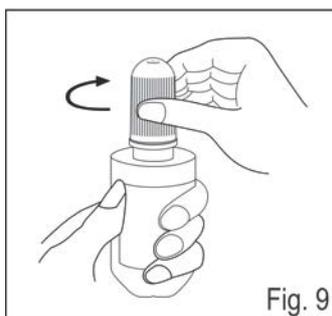


8. Turn the dropper container upside down and squeeze it gently to release one drop into each eye that needs treatment. Do not touch your eye or eyelid with the dropper tip (Fig. 8). If a drop misses your eye, try again.



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

9. Reclose the dropper container after use (Fig.9). Repeat in the other eye if needed. The next time you need to apply the drops follow steps 6-9



How much to use

- One or two drops in each eye four times a day, or as directed by your doctor
- If your symptoms worsen or do not improve, 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

You should keep using these drops if you are still around the things that you are allergic to. If you stop using Sodium Cromoglicate Eye drops your allergy symptoms may come back.

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 these drops.

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 out of the reach and sight 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 and 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.

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

6. FURTHER 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 or 10 ml plastic dropper bottle with a white plastic screw cap having a tamper-proof base ring.

Marketing Authorisation Holder and Manufacturer

Brown & Burk UK Ltd
5, Marryat Close
Hounslow West
Middlesex
TW4 5DQ
UK

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
PT: Cromoglicato de Sódio Brown 20mg/ml Colírio, solução

This leaflet was last approved in 01/2018.