Package leaflet: Information for the user

CATACROM® 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.

For brevity, this medicine will be referred to as Catacrom Eye Drops throughout this leaflet. Catacrom Eye Drops are available without prescription but you still need to take care to get the best results from them.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- · Keep this leaflet. You may need to read it again.
- · Ask your pharmacist if you need more information or advice.
- 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.
- · You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet

- I. What Catacrom Eye Drops are and what they are used for
- 2. What you need to know before you use Catacrom Eye Drops
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I. What Catacrom Eye Drops are and what they are used for

Catacrom Eye Drops are for the relief and treatment of allergic red, watery, itchy and puffy eyes caused by hayfever, house mites, and other causes of allergy such as pet hairs. Eye allergy can happen when sensitive eyes are exposed to these causes of allergy.

Catacrom Eye Drops is a medicine which affects cells called mast cells. It prevents them from releasing chemical substances which cause symptoms such as the redness, watering, itching and puffiness of allergic reactions.

These eye drops can be used by wearers of rigid or gas permeable contact lenses and can be used by people who are sensitive to preservatives in other kinds of eye drops.

2. What you need to know before you use Catacrom Eye Drops

Do not use Catacrom Eye Drops:

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

Warnings and precautions

Take special care with Catacrom Eye Drops:

Before using these eye drops, you must be sure that your eye irritation is the result of allergy (or you have been previously diagnosed by your doctor as suffering from allergy).

You can be confident that you have allergic eyes if:

- · both eyes are affected
- · you have a blocked or runny nose as well
- · your eyesight is not affected

but if:

- · you have no nose symptoms
- · only one eye is affected
- · your sight is affected

you cannot be sure that you are suffering from allergic eyes and you should talk to your doctor or pharmacist before using Catacrom Eye Drops.

Children

If you have any questions concerning the use of these eye drops in a child, or are unsure whether the child has allergic eyes, you should seek advice from your doctor or pharmacist.

Other medicines and Catacrom Eye Drops

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

If you have any questions about using these eye drops with other eye treatments, speak to your doctor or pharmacist.

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 using these eye drops. Your doctor or pharmacist may prefer a different treatment to be used under these circumstances.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

If there are changes to your vision after using these eye drops, wait until you can see clearly before driving or using machines.

3. How to use Catacrom Eye Drops

Catacrom Eye Drops are for use in the eye only.

Usual Dose

Catacrom Eye Drops are suitable for use in adults, the elderly and children.

The drops are in single-dose units. Put one or two drops into each eye four times a day, or as directed by your doctor. Avoid touching the eye with the dropper.

Read the instructions on the carton carefully. Wash your hands before and after you use these eye drops.

Steps for Using Catacrom Eye Drops

- I.Break off one unit dose container from the strip.
- 2. Open the unit dose container by bending/twisting the tab (Figure 1).
- 3. Tilt your head backwards.
- 4. Gently pull down the lower lid to form a pouch (Figure 2).
- 5. With the unit dose in the other hand, put one drop inside the pouch by gently squeezing the container. Try not to touch anything with the tip (Figure 3).
- 6. Close the eye for about 30 seconds and at the same time gently press a finger against the corner of the closed eye, nearest the nose. (Figure 4).











- 7. Some drops may roll down your face. This is normal. The eye holds less than one drop. Wipe away the excess with a clean tissue. If the drop of medication is not retained for any reason, another drop should be dropped into the eye
- 8. If you use more than one type of eye drop, wait five minutes before putting in the next one. This prevents the first drop from being washed away.
- 9. Repeat instructions 3-8 for the other eye.

If you use more Catacrom Eye Drops than you should There are no known effects of taking too much of this medicine. If you are concerned, please speak to your doctor or pharmacist.

If you forget to use Catacrom Eye Drops

If you forget to use this medicine, use it as soon as you remember.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Some people find that their eyes can become irritated or sting for a short while after taking these eye drops.

If the stinging lasts a long time, or is severe, you should talk to your doctor or pharmacist. Rarely, other symptoms of eye irritation have occurred.

If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor

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:

United Kingdom

Yellow Card Scheme

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 Catacrom Eye Drops

Keep out of the sight and reach of children.

Once opened, use the unit dose straight away and then throw away the container.

Do not use this medicine after the expiry date which is stated on the carton, sachet and unit dose after EXP. The expiry date refers to the last day of that month. Do not store above 25°C.

Store in the original package. After opening the sachet: use contents within 28 days.

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 Catacrom Eye Drops contain

- The active substance is sodium cromoglicate.
- · The other ingredients are purified water and sodium chloride.
- · Each individual single-dose unit contains 6 mg of sodium cromoglicate in 0.3 ml of solution.

What Catacrom Eye Drops look like and contents of the pack

Each unit dose container holds 0.3 ml Catacrom 2% Eye Drops without preservative and there are 10, 12, 18, 20, 24, 30 or 90 single-dose units in each carton. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer Catacrom Eye Drops are manufactured by:

Laboratoire Unither,

Espace Industriel Nord, 151 rue André Durouchez - CS 28028, 80084 Amiens Cedex 2, France,

Laboratoire Unither.

ZI de la Guérie 50211 Coutances Cedex. France.

Marketing Authorisation Holder:

Rayner Pharmaceuticals Limited, 10 Dominion Way, Worthing, West Sussex, BN14 8AQ, United Kingdom.

CATACROM is a registered trade mark.

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For package information leaflet in large font please go to www.xpil.medicines.org.uk.

For large print, audio or Braille versions contact the RNIB on the Medicine Leaflet Line 0800 198 5000.

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