

**PACKAGE LEAFLET:
INFORMATION FOR THE USER**

Rapitol® 2% w/v Eye Drops

nedocromil sodium

SANOPI 

 Is this leaflet hard to see or read?
Phone 0845 372 7101 for help

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. See section 4.

In this leaflet:

1. What Rapitol Eye Drops are and what they are used for
2. Before you use Rapitol Eye Drops
3. How to use Rapitol Eye Drops
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1. What Rapitol Eye Drops are and what they are used for



What Rapitol Eye Drops are

Rapitol 2% Eye Drops (called Rapitol Eye Drops in this leaflet) contain a medicine called nedocromil sodium. This belongs to a group of medicines called anti-allergics.

How Rapitol Eye Drops work

It works by stopping the release of the natural substances in your eyes that can lead to an allergic reaction.

What Rapitol Eye Drops can be used for

Stopping, treating and relieving the symptoms of 'allergic conjunctivitis' (inflammation of parts of the eye). Rapitol Eye Drops can be used for three types of allergic conjunctivitis:

- **'Perennial allergic conjunctivitis' in adults only:** This type of allergy can happen at any time of the year and is often caused by animal fur or house dust mites. Signs include itchy, watery, red or inflamed eyes and puffy eyelids.
- **'Seasonal allergic conjunctivitis' in adults and children:** This type of allergy, such as hay fever, can be caused by different pollens in different seasons of the year. Signs include itchy, watery, red or inflamed eyes and puffy eyelids.
- **'Vernal kerato conjunctivitis' in adults and children:** This is a more severe type of allergy. Signs include bumps inside the upper eyelid, sensitivity to light and severe itching

2. Before you use Rapitol eye drops



Do not use this medicine and tell your doctor or pharmacist if:

X You are allergic (hypersensitive) to nedocromil sodium, or any of the other ingredients of Rapitol Eye Drops (listed in Section 6 below).

Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue or around the eyes.

Do not use this medicine if the above applies to you. If you are not sure, talk to your doctor or pharmacist before using Rapitol Eye Drops.



Take special care with Rapitol Eye Drops if:

▲ You wear soft contact lenses. You should not wear soft contact lenses while using these drops.

If you are not sure if this applies to you, talk to your doctor or pharmacist before using Rapitol Eye Drops.

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

Your eyesight may be affected 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 Rapitol Eye Drops

Rapitol Eye Drops contain benzalkonium chloride. This may cause your eyes to become irritated. It may also change the colour of your contact lenses.

3. How to use Rapitol Eye Drops

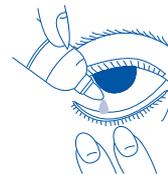
Always use Rapitol Eye Drops exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

Using this medicine

- If you wear hard or gas-permeable contact lenses, you should take them out while you use the eye drops. You should wait 15 minutes before you put the contact lenses back in
- If you need to use more than one type of eye medicine, the medicines must be used at least 5 minutes apart. Eye ointments should be used last.
- If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor or pharmacist

How to use this medicine

- Wash your hands
- Remove the cap from the bottle
- Tilt your head back
- Squeeze one or two drops inside the lower lid without touching your eye



Turn
Over



- Close your eye
- Wipe away any excess liquid from the eyes with a clean tissue
- Always put the cap back on the bottle as soon as you have used it
- Repeat in the other eye as needed

How much to use

Adults, Elderly and Children aged 6 years and over

Seasonal allergic conjunctivitis:

- One drop into each eye twice each day
- This can be increased to four times each day if needed
- Do not use for more than 12 weeks

Vernal kerato-conjunctivitis

- One drop into each eye four times each day

Adults and the Elderly only

Perennial allergic conjunctivitis:

- One drop into each eye twice each day
- This can be increased to four times each day if needed
- Use the drops regularly

Children under 6 years

This medicine is not recommended for children aged less than 6 years.

If you take more Rapitil Eye Drops than you should

If you use more Rapitil than you should, talk to your doctor or go to a hospital straight away. Remember to take any medicine that is left with you so the doctor knows what you have taken.

If you forget to use Rapitil 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 Rapitil Eye Drops

Keep using the eye drops for as long as your doctor or pharmacist advises you. If you stop using Rapitil Eye drops too early, 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, Rapitil Eye Drops can cause side effects, although not everybody gets them.

Stop using Rapitil 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:

Common (affects 1 to 10 people in a 100)

- 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
 - Change in the way things taste
- Uncommon (affects 1 to 10 people in a 1,000)
- Mild eye irritation

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Rapitil Eye Drops

Keep this medicine in a safe place where children cannot see or reach it.

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

Store below 25°C. Keep the bottle in the outer carton in order to protect from light.

Rapitil Eye Drops are sterile when you buy them, so you must not keep them 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 Rapitil Eye Drops contain

- The solution contains 2% w/v of the active substance, nedocromil sodium
- The other ingredients are disodium edetate, benzalkonium chloride, sodium chloride and Water for injections

What Rapitil Eye Drops look like and contents of the pack

Rapitil Eye Drops are available as a clear yellow solution supplied in a 3 ml or 5 ml plastic dropper bottle. Not all pack sizes may be marketed.



Marketing Authorisation Holder and Manufacturer

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This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

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