Package leaflet: Information for the patient

Relestat, 0.5 mg/ml, eye drops, solution

epinastine hydrochloride

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

1. What Relestat is and what it is used for

Relestat is an anti-allergic medicine.
It is an eye drops solution used to treat the **symptoms** of seasonal **allergic conjunctivitis**, a seasonal allergic disease affecting the eye. The main symptoms treated by Relestat include watery eyes and eyes or eyelids which are itchy, red or swollen.

2. What you need to know before you use Relestat

Do not use Relestat:
- **if you are allergic** to epinastine hydrochloride or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before using Relestat.

- **if you wear soft contact lenses**: you must remove them before using the Relestat eye drops. After using Relestat, wait at least 15 minutes before putting your lenses back in. See also in section 2, “Relestat contains benzalkonium chloride”.
- **if you have to use any other eye drops during treatment with Relestat**: leave at least 10 minutes between putting in Relestat and the other drops.

Other medicines and Relestat
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

If you have to use any other eye drops during treatment with Relestat, please see above under "Warnings and precautions" in this section.

Pregnancy and breast-feeding

Pregnancy
If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Breast-feeding
It is not known whether Relestat passes into breast milk. Ask your doctor or pharmacist for advice before using this medicine during breast-feeding.

Driving and using machines
Your sight may become blurred for a short time just after using Relestat. You should not drive or use machines until your sight is clear again.

Relestat contains benzalkonium chloride and phosphates
This medicine contains 0.5 mg benzalkonium chloride in each 5 ml of solution which is equivalent to 0.1 mg/ml.

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.

This medicine contains 23.75 mg phosphates in each 5 ml, which is equivalent to 4.75 mg/ml.
If you suffer from severe damage to the clear layer at the front of the eye (the cornea), phosphates may cause in very rare cases cloudy patches on the cornea due to calcium build-up during treatment (see section 4).

3. How to use Relestat

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

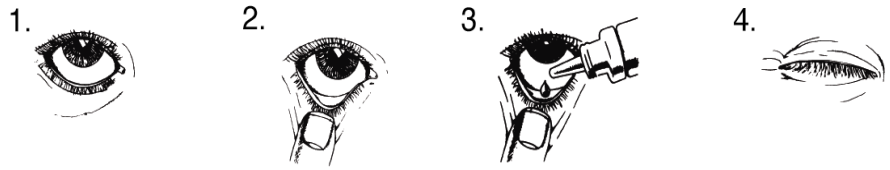
Use in children
Relestat should not be used in children below 12 years of age.

Use in adults and adolescents (12 years of age and older)

The recommended dose is **1 drop** in **each eye** that needs treatment, **twice a day**, for example in the morning and in the evening.

You should use Relestat every day that you experience eye symptoms during the allergy season but for **no longer than 8 weeks**.

Instructions for use
You must not use the bottle if the tamper-proof seal on the bottle neck is broken before you first begin to use it. Apply your eye drops in the following way:



1. Wash your hands. Tilt your head back and look at the ceiling.
2. Gently pull the lower eyelid down until there is a small "pocket".
3. Turn the bottle upside down and squeeze it to release one drop into each eye that needs treatment.
4. Let go of the lower lid, and close your eye for 30 seconds. If a drop misses your eye, try again.

To avoid contamination of the solution in the bottle, do not let the tip of the dropper touch your eye or anything else.
Replace and tighten the cap straight after use.
Wipe off any excess liquid from your cheek with a clean tissue.

The proper application of your eye drops is very important. If you have any questions ask your doctor or pharmacist.

If you use more Relestat than you should
If you use more drops of Relestat than you should**,** it is unlikely to cause you any harm. Put your next drop(s) in at the usual time. If you are worried, talk to your doctor or pharmacist.

If you forget to use Relestat
If you forget a dose apply it as soon as you remember, unless it is almost time for your next dose, in which case you should miss out the forgotten dose. Then, use your next dose at the usual time and continue with your normal routine.

Do not use a double dose to make up for a forgotten dose.

If you stop using Relestat
Relestat should be used as advised by your doctor. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. None of the side effects are likely to be serious; most side effects are likely to be mild and only affect the eye.

If the following happens, stop using Relestat and contact your doctor immediately or go to your nearest hospital:

- asthma (an allergic disease affecting the lungs that causes breathing difficulties)
- if you experience symptoms of angioedema (swelling of face, tongue or throat; difficulty
- swallowing; hives and breathing difficulties)

The following side effects may also occur:

Common (may affect up to 1 in 10 people)
•burning sensation or irritation of the eye (mostly mild)

Uncommon (may affect up to 1 in 100 people)
General side effects:
- headache
- swelling and irritation inside the nose, which may cause a runny or blocked nose and sneezing
- unusual taste in your mouth

Side effects affecting the eye:
- red eyes
- dry eyes
- itchy eyes
- difficulty in seeing clearly
- discharge from the eyes

Not known (frequency cannot be estimated from the available data):
increased tear production
- eye pain
- allergic reaction affecting the eyes
- swelling of the eyes
- swelling of the eyelids
- skin rash and redness

Other side effects reported with eye drops containing phosphate
This medicine contains 23.75 mg phosphates in each 5 ml which is equivalent to 4.75 mg/ml.
If you suffer from severe damage to the clear layer at the front of the eye (the cornea), phosphates may cause in very rare cases cloudy patches on the cornea due to calcium build-up during treatment (see section 2).

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, 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 Relestat

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

Do not use this medicine after the expiry date which is stated on the label of the bottle and on the box after EXP.

Do not use this medicine if you notice that the eye drops have shown signs of deterioration, for example change in colour, and take the product back to your pharmacist.

Do not store above 25°C.

Keep the bottle in the box in order to protect from light.

You must **throw away the bottle 28 days after you first opened it**, even if there are still some drops left. This will guard against infection. To help you remember, write down the date that you opened it in the space on the box.

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 Relestat contains

- The active substance is epinastine hydrochloride. One ml of eye drops, solution, contains 0.5 mg of epinastine hydrochloride.
- The other ingredients are benzalkonium chloride (a preservative), disodium edetate, sodium chloride, sodium dihydrogen phosphate dihydrate, sodium hydroxide/hydrochloric acid (to adjust pH) and purified water.

What Relestat looks like and contents of the pack

Relestat is a clear and colourless eye drops solution in a plastic bottle with a screw-cap. When unopened, each bottle is about half full and contains 5 ml of solution.

Each pack contains 1 bottle.

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

Name of the Member State	Name of the medicinal product
Austria, Belgium, Denmark, Germany, Greece, Hungary, Ireland, Italy, Luxemburg, Netherlands, Portugal, Spain, Sweden, United Kingdom	RELESTAT
Czech Republic, France, Slovak Republic	PURIVIST

This leaflet was last revised in August 2025

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