

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS'
REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Relestat

Ophthalmic Solution

Active ingredient and its concentration:

Each ml contains: 0.5 mg epinastine hydrochloride

For a full list of ingredients and allergens see section 2 - subsection "Important information about some of the ingredients of Relestat" and section 6 "Further information".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

1. What is this medicine intended for?

Relestat is an anti-allergic medicine.

It is a solution for the eyes 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.

Therapeutic group:

Decongestants and anti-allergy drugs (antihistamines).

2. Before using the medicine

Do not use this medicine if:

you are sensitive (allergic) to epinastine hydrochloride or any of the other ingredients of this medicine (listed in section 6).
--

Special warnings regarding use of this medicine

Before using Relestat, tell your doctor if:

- **you wear soft contact lenses:** you must remove them before using the Relestat solution. After using Relestat, wait at least 15 minutes before putting your lenses back in. See also in Section 2: "Important information about some of the ingredients of Relestat".
- **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.

Use in children

Do not use Relestat in children under 12 years old.

Interactions with other medicines

If you are taking, or if you took lately, other medicines, including non-prescription medicines and food supplements, tell the doctor or pharmacist.

If you have to use any other eye drops during treatment with Relestat, please see above under "Special warnings regarding use of this medicine" 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 unknown 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 blurry for a short time just after using Relestat. You should not drive or use machines until your sight is clear again.

Important information about some of the ingredients of Relestat:

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.

Relestat contains a preservative, called benzalkonium chloride, that may be absorbed by soft contact lenses and may change the colour of the contact lenses.

If you wear soft contact lenses (also called hydrophilic lenses), you must remove them before using the Relestat eye drops. After using Relestat, you have to wait at least 15 minutes before putting your lenses back in.

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 should you use the medicine?

Always use according to the doctor's instructions.

Check with the doctor or pharmacist if you are not sure about your dosage or about how to take this medicine.

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

The dosage and treatment will be determined by the doctor only. The standard dosage 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 symptoms during allergy season but for **no longer than 8 weeks**.

Do not exceed the recommended dose.

Do not swallow! For external use only.

Instructions for use

You must not use the bottle if the tamper-proof seal at the neck of the bottle 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. Using your index finger 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 the 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 the 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 refer to your doctor or pharmacist.

If you accidentally took a higher dosage

If you use more Relestat solution 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, consult your doctor or pharmacist.

If a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.

If you forget to take the medicine

If you forget a dose, apply it as soon as you remember, unless it is almost time for your next dose. In such a 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 apply a double dose to make up for a forgotten dose.

Be sure to adhere to the treatment as recommended by the doctor.

If you stop using Relestat

Relestat should be used as advised by your doctor.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

As with any medicine, use of Relestat may cause side effects in some users. Do not be alarmed by the list of side effects. You may not experience any of them.

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

- 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).

Additional side effects

Common side effects (may affect 1-10 in 100 users)

- burning sensation or irritation in the eye (mostly mild).

Uncommon side effects (may affect 1-10 in 1000 users)

General side effects:

- headache
- swelling and irritation inside the nose which may cause a runny or blocked nose and sneezing
- unusual taste in the mouth

Side effects affecting the eye:

- red eyes
- dry eyes
- itchy eyes
- difficulty in seeing clearly
- discharge from the eyes

Side effects of **unknown frequency** (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).

If a side effect appeared, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, you must consult with the doctor.

You can report side effects to the Ministry of Health by clicking on the link: "Reporting side effects due to medical treatment" that is found on the homepage of the Ministry of Health website (www.health.gov.il) and using the online form for reporting side effects, or by using the link:

5. How should the medicine be stored?

Avoid poisoning! This medicine, and all other medicines, must be stored in a closed place out of the reach and sight of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use the medicine after the expiry date (exp. date) which is stated on the label of the bottle and on the box. The expiry date refers to the last day of that month.

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 **a month 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. Additional information

In addition to the active ingredient, the medicine also contains:

Sodium dihydrogen phosphate dihydrate, sodium chloride, disodium edetate, benzalkonium chloride (a preservative), 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 solution for the eyes 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 one bottle.

Registration holder :

Allergan Israel Ltd., 32 Shacham st., Petach Tikva 4951727.

Manufacturer:

Allergan Pharmaceuticals Ireland, Westport, Ireland.

Revised in April 2021 according to guidelines of Ministry of Health

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 133-58-31028

