

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

The medicine is dispensed with a doctor's prescription only

## **Relestat<sup>®</sup>** **Ophthalmic Solution**

### **Active ingredient and its concentration:**

epinastine hydrochloride 0.05% w/v

Inactive ingredients and allergens in this medicine: see section 2 under "Important information about some of this medicine's ingredients", and section 6 "Additional information".

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

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

### **1. What is this medicine intended for?**

For treatment of the symptoms of seasonal allergic conjunctivitis.

**Therapeutic group:** Decongestants and anti-allergy drugs (antihistamines).

Seasonal allergic conjunctivitis is 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. Before using the medicine**

#### **Do not use this medicine if:**

you are sensitive (allergic) to the active ingredient epinastine hydrochloride or to any of the other ingredients in this medicine (listed in section 6 – "Additional information").

### **Special warnings about using 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 Section 2 - "Important information about some of this medicine's ingredients".
- **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.

### **Children and adolescents**

Do not use Relestat in children under 12 years old.

### **Drug interactions**

**If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist.**

If you have to use any other eye drops during treatment with Relestat, please see under “Special warnings about using this medicine” in this section.

### **Pregnancy, breast-feeding, and fertility**

#### 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.

#### Fertility

There is insufficient information about the effect of Relestat on fertility.

### **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 this medicine’s ingredients**

#### **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 to use this medicine?**

Always use this medicine according to your doctor’s instructions.

Check with your doctor or pharmacist if you are not sure about the dosage and treatment regimen of 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 recommended dosage is usually **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. 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 have accidentally taken a higher dose**

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 some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package 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 skip 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.

Adhere to the treatment as recommended by your doctor.

**If you stop using this medicine**

Relestat should be used as advised by your doctor.

**Do not take medicines in the dark! Check the label and the dose every 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, using Relestat may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

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

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

#### **Additional side effects**

**Common** side effects (effects that occur in 1-10 in 100 users)

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

**Uncommon** side effects (effects that occur in 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** (the frequency of these effects has not been established yet)

- 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 you experience a side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.**

### Reporting side effects

You can report side effects to the Ministry of Health by clicking on the link "Reporting Side Effects of Drug Treatment" that is found on the homepage of the Ministry of Health website ([www.health.gov.il](http://www.health.gov.il)) which links to an online form for reporting side effects, or by using the link: <https://sideeffects.health.gov.il>

### **5. How to store the medicine?**

Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. 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 outer carton. 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 outer carton 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 outer carton.

Do not throw away any medicine via wastewater or household waste. Ask the 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, this medicine also contains:**

sodium dihydrogen phosphate dihydrate, sodium chloride, disodium edetate, benzalkonium chloride, hydrochloric acid and/or sodium hydroxide (to adjust pH) and purified water.

### **What Relestat looks like and contents of the pack**

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.

**Manufacturer:** Allergan Pharmaceuticals Ireland, Castlebar Road, Westport, County Mayo, Ireland.

**Registration holder's name and address:** AbbVie Biopharmaceuticals Ltd., 4 Haharash St., Hod Hasharon, Israel.

Revised in March 2023 according to MOH guidelines.

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