



0.5 mg/ml, eye drops, solution
Epinastine hydrochloride

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 further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

In this leaflet:

1. What RELESTAT™ is and what it is used for
2. Before you use RELESTAT™
3. How to use RELESTAT™
4. Possible side effects
5. Storing RELESTAT™
6. Further information

RELESTAT™, 0.5 mg/ml, eye drops, solution
Epinastine hydrochloride

- The active substance is epinastine hydrochloride 0.5 mg/ml.
- 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.

The marketing authorisation holder and the manufacturer is
Allergan Pharmaceuticals Ireland
Castlebar Road, Westport, Co Mayo, Ireland

1. WHAT RELESTAT™ IS AND WHAT IT IS USED FOR

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

RELESTAT™ contains an antihistamine, which is an antiallergic agent. It is used for the treatment of the symptoms of seasonal allergic conjunctivitis, also known as hayfever (itchy, red, watery or swollen eyes and/or eyelids).

2. BEFORE YOU USE RELESTAT™

Do not use RELESTAT™:

- If you are hypersensitive (allergic) to epinastine hydrochloride or any of the other ingredients.

Take special care with RELESTAT™:

- If you wear contact lenses.
Do not use the drops while you are wearing your lenses. Wait 10-15 minutes after using the drops before you put your lenses back in. A preservative in RELESTAT™ called benzalkonium chloride can discolour soft contact lenses.

Pregnancy

There is limited experience from use during pregnancy. If you are pregnant or if you suspect you may be pregnant, contact your doctor or pharmacist for advice before using RELESTAT™.

Breast-feeding

It is not known whether RELESTAT™ passes into breast milk. Ask your doctor or pharmacist for advice before use during breastfeeding.

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.

Using other medicines

Please inform your doctor or pharmacist if you are taking, or have recently taken, any other medicines, even those not prescribed.

3. HOW TO USE RELESTAT™

Always use RELESTAT™ exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dosage is one drop of RELESTAT™ in each affected eye, twice a day (in the morning and in the evening).

No change in the dosage is required for adolescents (aged 12 to 18 years), elderly patients (over 65 years of age), or if you have kidney or liver problems.

You should use RELESTAT™ every day that you experience symptoms during the allergy season for up to 8 weeks.

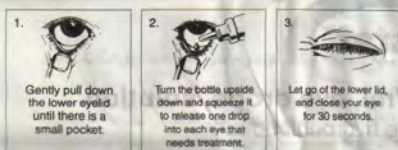
If you use RELESTAT™ together with other eye drops, leave at least ten minutes between putting in RELESTAT™ and the other drops.

To use RELESTAT™:

You must not use the bottle if the tamper-proof seal on the bottle neck is broken before you first begin to use it.

Wash your hands before opening the bottle. Tilt your head back and look at the ceiling.

✓ seal



If a drop misses your eye, try again.

To help prevent infection, do not let the tip of the bottle touch your eye, the surrounding tissue or anything else. Put the screw-cap back on to close the bottle, straight after you have used it.

If you use more 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™, use a single drop in each eye that needs treatment as soon as you remember, and then go back to your regular routine. Do not take a double dose to make up for forgotten individual doses.

4. POSSIBLE SIDE EFFECTS

Like all medicines, RELESTAT™ can have side effects. None of the side effects is likely to be serious and most side effects are likely to be mild and only affect the eye.

Common side effect

The only common side effect is burning sensation in the eye (mostly mild). This may affect up to nine people in every 100 people.

Uncommon side effects

The following side effects are all uncommon and may affect up to 1 person in every 100 people.

Side effects affecting the eye:

- allergic reaction in the eye
- drooping eyelid
- swollen eyes
- red eyes
- dry eyes
- irritated eyes
- itchy eyes
- increased eye sensitivity
- sensitivity to light
- stinging eyes
- difficulty in seeing clearly
- discharge from the eyes

Side effects affecting the body:

- asthma (breathing difficulties)
- headache
- irritated nose
- dry mouth
- itching
- hinitis
- unusual taste in your mouth.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. STORING RELESTAT™

Keep out of the reach and sight of children.

Do not store above 25°C.

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

You must throw away the bottle four weeks 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 use RELESTAT™ after the expiry date (marked 'EXP:') stated on the label of the bottle and the box.

Do not use RELESTAT™ if the drops become discoloured or show any signs of deterioration and take the product back to the pharmacist.

This leaflet was last approved during April 2010.

(THIS IS A MEDICAMENT)

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children
Council of Arab Health Ministers
Union of Arab Pharmacists

 **ALLERGAN**

Westport, Co. Mayo, Ireland

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