

RELESTAT™ OPHTHALMIC SOLUTION

epinastine hydrochloride (0.5 mg/mL)

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What **RELESTAT™** is used for

RELESTAT™ is an anti-allergic medicine.

It is an eye drops solution used to prevent itching associated with allergic disease affecting the eye.

How **RELESTAT™** works

RELESTAT™ blocks the release of histamine from certain cells and works locally in the eye.

Before you use **RELESTAT™**

- When you must not use it

- If you are allergic (hypersensitive) to: epinastine hydrochloride or any of the other ingredients of **RELESTAT™** listed in Section "Product Description".

- Pregnancy and breast-feeding:

- If you are pregnant or if you think you may be pregnant, ask 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 using **RELESTAT™** during breast-feeding.

- Before you start use it

Take special care with **RELESTAT™**.

RELESTAT™ contains a preservative, called benzalkonium chloride that can discolour soft contact lenses and may cause eye irritation.

If you wear soft contact lenses: you must remove them before using the **RELESTAT™** eye drops.

After using **RELESTAT™**, wait at least 10 minutes before putting your lenses back in.

- Taking other medicine

Please tell your doctor or pharmacist if you are using or have recently used any other medicines, including medicines obtained without a prescription.

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.

How to use **RELESTAT™**

- How much to use

Always use **RELESTAT™** exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. **RELESTAT™** is used on the eye only.

The usual dose of **RELESTAT™** for adult is 1 drop in each eye that needs treatment, twice a day, for example in the morning and in the evening.

Children and Adolescents

RELESTAT™ may be used in children and adolescents (3 years of age and older) at the same dosage as in adults.

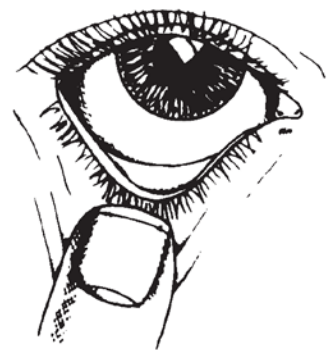
Instructions for use

When using the bottle for the first time, turn the screw-cap clockwise as far as possible, so the dropper tip is pierced.

The bottle is now ready for use. The screw-cap can then be removed by turning it in an anticlockwise direction.

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

1. Gently pull down the lower eyelid of the eye that needs treatment until there is a small "pocket".



2. Turn the bottle upside down. Squeeze it to release 1 drop into the "pocket".



3. Let go of the lower lid, and close your eye for 30 seconds.



4. Repeat the steps 1 to 3 for the other eye, if it also needs treatment.

If a drop misses your eye, try again.

To help prevent contamination, do not let the tip of the bottle touch your eye, the surrounding tissue or anything else. Serious damage to the eye and subsequent loss of vision may result from using contaminated solutions. Put the screw-cap back on to close the bottle, straight after you have used it.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Use as directed by your doctor or pharmacist. There is no experience with the use of **RELESTAT™** ophthalmic solution for more than 8 weeks.

- If you forget to use it

If you forget a dose, use **RELESTAT™** as soon as you remember, unless it is almost time for your next dose. In this 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 have any further questions on the use of this product, ask your doctor or pharmacist.

- If you use too much (overdose)

If you use more drops of **RELESTAT™** than you should, it may cause reversible constriction of pupil. Put your next drop(s) in at the usual time. If you are worried, talk to your doctor or pharmacist.

While you are using it

- Things you must do

Tell all the doctors, dentists and pharmacists treating you that you are taking **RELESTAT™**.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give **RELESTAT™** to anyone else, even if they have the same symptoms or condition as you.

Do not wear contact lens if your eyes are red.

- Things to be careful of

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.

Side effects

Like all medicines, **RELESTAT™** 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.

The most frequently reported adverse reaction occurring in approximately 5% of individuals was burning

sensation/eye irritation. Other ocular adverse reactions reported in less than 1% of individuals include eye redness, eye discharge, eye dryness, eye itchiness and visual disturbance.

The most frequently reported non-ocular adverse reactions included headache and stuffy or runny nose occurring in approximately 3% and 2% of individuals respectively. Additional non-ocular adverse reactions reported in less than 1% of individuals included asthma, nose irritation and distorted sense of taste.

Some of these events were similar to the underlying disease being studied. 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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI))

Storage and Disposal of RELESTAT™

- Storage

Keep out of the reach and sight of children.

Do not use **RELESTAT™** after the expiry date which is stated on the label of the bottle and on the box after EXP.

Do not use **RELESTAT™** 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.

Store below 30°C

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

- Disposal

18/05/2018

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.

Serial Number:

NPRA(R4/1)190418/00113

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.

Product Description

- What it looks like

RELESTAT™ is a clear and colourless eye drops solution in an opaque white plastic bottle with a screw cap. When unopened, each bottle contains 5 ml of solution in 10ml bottle.

Each pack contains 1 bottle.

- Ingredients

- Active ingredient:
epinastine hydrochloride
- Inactive ingredients:
benzalkonium chloride, edetate disodium, sodium chloride, sodium phosphate monobasic dihydrate, sodium hydroxide, hydrochloric acid and purified water

- MAL number:

MAL20112151AZ

Manufacturer

Allergan Pharmaceuticals Ireland
Castlebar Road, Westport
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Ireland

Product Registration Holder

Allergan Malaysia Sdn Bhd
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Date of revision