PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

Schedule 2

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

RELESTAT, epinastine hydrochloride 0,5 mg/ml, eye drops

Read all of this leaflet carefully because it contains important information for you.

RELESTAT is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use RELESTAT carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share RELESTAT with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if you symptoms worsen or do not improve after 10 days.

1. WHAT RELESTAT CONTAINS

The active substance is epinastine hydrochloride. One ml of eye drop solution contains 0,5 mg of epinastine hydrochloride.

The other ingredients are benzalkonium chloride 0,01 % *m/v* (a preservative), disodium edetate, sodium chloride, sodium dihydrogen phosphate dehydrate and purified water.

2. WHAT RELESTAT IS USED FOR

RELESTAT is an anti-allergic eye drop 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.

3. BEFORE YOU USE RELESTAT

Do NOT use RELESTAT:

- If you are allergic (hypersensitive) to epinastine hydrochloride, benzakonium chloride, or any of the other ingredients of RELESTAT listed in section "WHAT RELESTAT CONTAINS".

Take special care with RELESTAT:

- RELESTAT is a topical eye drop and should not be injected or taken orally;
- **If you wear soft contact lenses:** you must remove them before using RELESTAT eye drops. After using RELESTAT, wait at least 15 minutes before putting your lenses back in. See also “Important information about some of the ingredients of RELESTAT”;
- **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.

Pregnancy and breastfeeding

RELESTAT should not be used if you are pregnant or breastfeeding your baby. It is not known whether RELESTAT passes into breast milk. If you are using RELESTAT you should not breastfeed your baby.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before using RELESTAT.

Driving and using machinery

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.

Important information about some of the ingredients in RELESTAT

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

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.

Using other medicines with RELESTAT

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

4. HOW TO USE RELESTAT

Do not share medicines prescribed for you with any other person. Always use RELESTAT exactly as your doctor or pharmacist has instructed you. You should check with your doctor or

pharmacist if you are unsure.

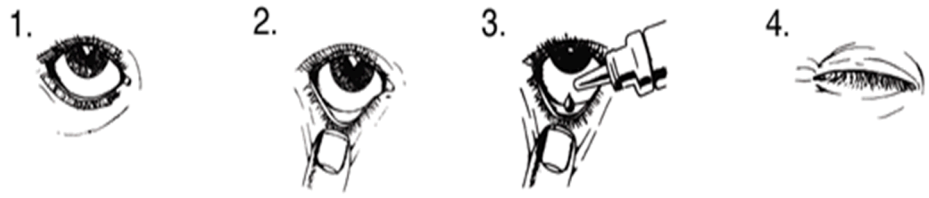
RELESTAT should not be used in children below 12 years of age.

If you have the impression that the effect of the RELESTAT is too strong or too weak for you, tell your doctor or pharmacist.

Adults and adolescents (12 years of age and older)
The usual dose of RELESTAT 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 not for longer than 8 weeks (see Take special care with RELESTAT).

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 before opening the bottle. 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.

To avoid contamination of the solution in the bottle, do not let the tip of the bottle touch your eye or anything else. Replace and tighten the cap straight after use. Wipe off any excess liquid form 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. However if you are worried, consult to your doctor or pharmacist.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to use RELESTAT

If you forgot 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 or pharmacist.
If you have any further questions on the use of RELESTAT, ask your doctor or pharmacist.

5. POSSIBLE SIDE EFFECTS

RELESTAT can have side effects.

Not all side effects reported for RELESTAT are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using RELESTAT, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop using RELESTAT and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Severe allergic (hypersensitive) reaction with symptoms such as skin rash, which can be red and itchy, swelling of the eyes, throat or face;
- Asthma (an allergic disease affecting the lungs that causes breathing difficulties).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to RELESTAT. You may need urgent medical attention or hospitalisation.

The following side effects may also occur:

Frequent side effects

- Burning sensation or irritation of the eye (mostly mild)

Less frequent side effects

General side effects:

- Headache
- Swelling and irritation inside the nose, which may cause a runny or blocked nose and sneezing
- Sinus infection
- Unusual taste in your mouth

Side effects affecting the eye:

- Red eyes
- Dry eyes
- Itchy eyes
- Difficulty in seeing clearly
- Discharge from the eyes

Patients have also reported the following side effects:

Eye disorders

Ocular hyperemia, lacrimation increased, eye pain, eye swelling, eyelid edema

Immune system disorders

Hypersensitivity reaction including symptoms or signs of eye allergy and skin allergic reaction

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

You can report side effect to SAHPRA via “6.04 Adverse Drug Reactions Reporting Form”, found online under SAHPRA’s publication: https://www.sahpra.org.za/Publications/Index/8
By reporting side effects, you can help provide more information on the safety of RELESTAT.
You can also report side effects to AbbVie (Pty) Ltd by sending an e-mail to MEAPV@abbvie.com

6. STORING AND DISPOSING OF RELESTAT

Store at or below 25 °C.

Do not use the eye drops more than 30 days after opening.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN. Do not use the medicine after the expiry date printed on the bottle and the box. Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

7. PRESENTATION OF RELESTAT

5 ml LDPE bottle with a dropper insert and a white polystyrene screw cap.

8. IDENTIFICATION OF RELESTAT

RELESTAT is a clear and colourless eye drop solution in a multi-dose bottle with a screw-cap.

9. REGISTRATION NUMBER

37/15.4/0691

10. NAME AND ADDRESS OF THE REGISTRATION HOLDER

AbbVie (Pty) Ltd
Building 7
Waterfall Corporate Campus
74 Waterfall Drive
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11. DATE OF PUBLICATION

Date of registration: 11 August 2006

Date of most recent patient information leaflet as approved by Council: 21 April 2023

For the professional information please email medicalinfo.za@abbvie.com