Package leaflet: Information for the user

AzelastinehydrochlorideDevatis 0,5 mg/ml, oogdruppels, oplossing in verpakking voor éénmalig gebruik
Azelastinehydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 2 days.

What is in this leaflet

1. What Azelastine Devatis is and what it is used for

Azelastine Devatis contains azelastine which belongs to a group of medicines called antihistamines. Antihistamines work by preventing the effects of substances such as histamine that the body produces as part of an allergic reaction. Azelastine has been shown to reduce inflammation of the eye.

Azelastine Devatis is used to treat and prevent the ocular symptoms of hay fever (seasonal allergic conjunctivitis), in adults and children age 4 years and above.

Azelastine Devatis is used for eye disorders caused by an allergy to substances such as house dust mites or animal hair (perennial allergic conjunctivitis) in adults and children age 12 years and above.

2. What you need to know before you use Azelastine Devatis

Do not use:
- If you are allergic (hypersensitive) to azelastine hydrochloride or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before using Azelastine Devatis

- If you are not sure whether your eye symptoms are caused by an allergy. In particular, if only one eye is affected, your vision is impaired or the eye hurts and you do not have any symptoms in your nose, you may have an infection rather than an allergy.

- If the symptoms worsen or last longer than 48 hours without remarkable improvement despite the use of Azelastine Devatis.

Azelastine Devatis is not suitable for treating eye infections.

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

It is not known if Azelastine Devatis reacts with any other medicines.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Driving and using machines
If you have a transient blurring of vision after using Azelastine Devatis, you should wait until your sight clears before driving or operating machinery.

3. How to use Azelastine Devatis

Always use Azelastine Devatis exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Ocular symptoms of hay fever (seasonal allergic conjunctivitis)
The usual dose for seasonal allergic conjunctivitis in adults and children aged 4 years and above is one drop in each eye in the morning and the evening.

If you anticipate contact with pollen, the usual dose of Azelastine Devatis may be taken as a preventive measure before going outside.

Ocular symptoms of allergy due to, for example house dust mite or dog and cat hairs (perennial allergic conjunctivitis)
The usual dose for non-seasonal allergic conjunctivitis in adults and children aged 12 years and above is one drop in each eye in the morning and evening.

Use in children
The safety and efficacy of Azelastine Devatis 0.5 mg/ml eye drops, solution in children aged less than 4 years has not been established.

Do not take Azelastine Devatis for more than 6 weeks. Azelastine Devatis should only be applied to the eyes.

If your symptoms are severe, the dose can be increased to one drop in each eye, up to four times a day.

Do not allow the tip of the single-dose container to touch your eye or areas around your eye. It may become contaminated with bacteria that can cause eye infections leading to serious damage of the eye, even loss of vision. To avoid possible contamination of the single-dose container, keep the tip of the container away from contact with any surface.

The solution from one individual single-dose container of Azelastine Devatis is to be used immediately after opening for administration to the affected eye(s). Since sterility cannot be

maintained after the individual single-dose container is opened, a new container must be opened prior to each use and must be discarded immediately after administration.

How to use Azelastine Devatis

1. Wash your hands before using the drops.
2. Remove the top from the single-dose container.
3. Make sure that the tip of the single-dose container does not touch anything.
   Hold the single-dose container in one hand between the thumb and forefinger. Tilt your head back, and use your other forefinger to pull down the lower eyelid.
4. Place the dropper tip close to your eye, but not touching the eye or lid, and gently squeeze the single-dose container to release one drop into your eye.
5. Close your eyelid and gently press the corner of your eye with your forefinger for one minute.
6. After instillation, discard the used single-dose container even if there is solution remaining.
7. Store the remaining single-dose containers in the sachet; the remaining single-dose containers must be used within 28 days after opening of the sachet.

Follow these instructions carefully. Consult your doctor or pharmacist if there is anything you do not understand.

If you use more Azelastine Devatis than you should
If you put too much Azelastine Devatis into your eyes you are unlikely to have any problems. If you are worried, contact your doctor. If you accidentally swallow Azelastine Devatis, contact your doctor as soon as possible.

If you forget to use Azelastine Devatis
Use your eye drops as soon as you remember, then take the next dose at the usual time.
Do not take a double dose to make up for a missed dose.

If you stop using Azelastine Devatis
If you interrupt the use of Azelastine Devatis your symptoms are likely to return.

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

4. Possible side effects

Like all medicines, Azelastine Devatis can cause side effects, although not everybody gets them.

Common (may affect upto 1 in 10 users): Slight irritation (burning, itching, watering) in the eyes after putting in Azelastine Devatis. This should not last long.

Uncommon (may affect upto 1 in 100 users): Bitter taste in your mouth.

Very rare (may affect less than 1 10,000 users): Allergic reaction (such as rash and itching).

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V*. By reporting side effects, you can help provide more information on the safety of this medicine.

[*For the printed material, please refer to the guidance of the annotated QRD template.]

5. How to store Azelastine Devatis

Store in the original package. Do not refrigerate or freeze.
After first opening of the sachet: use the single dose containers within 28 days.
After first opening of the single-dose container: use immediately and discard the single-dose container after use.
Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

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. Contents of the pack and other information

What Azelastine Devatis contains
- The active substance is is azelastine hydrochloride, 0.5 mg/ml.
- The other ingredients are sorbitol, liquid (cristallizing) (420), hypromellose (E464), disodium edetate (E386), sodium hydroxide (E524) and water for injections.

What Azelastine Devatis looks like and contents of the pack

Azelastine Devatis is a clear, colourless to nearly colourless, slightly viscous solution.
It is supplied in 0.3 ml single-dose containers in sachets. Each sachet contains 5 single-dose containers.

Azelastine Devatis is available in pack-sizes of 5 x 0.3 ml, 10 x 0.3 ml, 20 x 0.3 ml, 30 x 0.3 ml, 50 x 0.3 ml, 60 x 0.3 ml and 120 x 0.3 ml single dose containers.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Devatis GmbH
Spitalstr. 22
79539 Lörrach
Duitsland

Dit geneesmiddel is in het register ingeschreven onder: RVG 113365

This medicinal product is authorised in the Member States of the EEA under the following names:

Nederland	Azelastinehydrochloride Devatis 0,5mg/ml, oogdruppels, oplossing in verpakking voor éénmalig gebruik

Deze bijsluiter is voor het laatst goedgekeurd in november 2019