

Azep[®] Nasal Spray

azelastine hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about AZEP NASAL SPRAY. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What AZEP NASAL SPRAY is used for

AZEP NASAL SPRAY is used to relieve runny nose, sneezing, itching or blocked nose caused by allergies, such as to pollen (hay fever) house dust mites or pet hair.

AZEP NASAL SPRAY belongs to a group of medicines called antihistamines. It works by blocking the action of histamine and other substances produced by the body, which are causing your allergies.

AZEP NASAL SPRAY is not addictive.

Before you use AZEP NASAL SPRAY

When you must not use it

Do not use AZEP NASAL SPRAY if you have an allergy to AZEP

NASAL SPRAY or any of the ingredients listed at the end of this leaflet.

Do not give AZEP NASAL SPRAY to a child under 5 years, unless directed by the child's doctor.

The safety and effectiveness of AZEP NASAL SPRAY in children under 5 years have not been established.

Do not use AZEP NASAL SPRAY after the expiry date printed on the pack.

If you use this medicine after the expiry date has passed, it may not work as well.

Do not use AZEP NASAL SPRAY if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start using AZEP NASAL SPRAY contact your doctor or pharmacist.

Before you start to use it

Tell your doctor or pharmacist if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor or pharmacist if you have or have had any medical conditions, especially the following:

- Kidney disease

Tell your doctor or pharmacist if you are pregnant or intend to become pregnant, or are breastfeeding.

Your doctor or pharmacist will discuss the possible risks and benefits of using AZEP NASAL SPRAY during pregnancy and breastfeeding.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and AZEP NASAL SPRAY may interfere with each other if a significant amount of the nasal spray is absorbed in your body. These include:

- cimetidine, a medicine used to treat stomach ulcers and some other stomach conditions.

These medicines may be affected by AZEP NASAL SPRAY, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor or pharmacist will advise you.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while using AZEP NASAL SPRAY.

How to use AZEP NASAL SPRAY

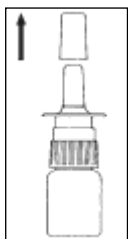
Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box or bottle, ask your doctor or pharmacist for help.

How much to use

Use one spray of AZEP NASAL SPRAY in each nostril, every 12 hours as necessary.



How to use it

Blow your nose gently, to clear away any mucus.



1. Remove the protective cap.
2. Before first use, prime the spray by pressing the pump 2-3 times until an even spray emerges.



3. Tilt your head forwards (look at your toes). Spray once into each nostril, closing the other nostril with one finger. Sniff slowly and gently.
4. Wipe the nozzle and replace the protective cap.

Prime the pump again if you have not used the spray for 3 or more days.

How long to use it

AZEP NASAL SPRAY can be used for up to 6 months for seasonal and non-seasonal allergies.

Consult your doctor if your symptoms have not cleared up after 6 months.

If you forget to use it

AZEP NASAL SPRAY should be used only when necessary.

Do not use a double dose to make up for the dose that you missed.

If you use too much (overdose)

Immediately telephone your doctor or pharmacist or the Poisons Information Centre (phone 13 11 26), if you think that you or anyone else may have used too much AZEP NASAL SPRAY, or if anyone accidentally drinks AZEP NASAL SPRAY. Do this even if there are no signs of discomfort or poisoning.

If AZEP NASAL SPRAY is accidentally sprayed into the eyes, bathe them with plenty of water.

They may sting for a while.

While you are using AZEP NASAL SPRAY

Things you must do

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are using AZEP NASAL SPRAY.

Tell any other doctors, dentists and pharmacists who are treating you that you are using AZEP NASAL SPRAY.

If you become pregnant while using AZEP NASAL SPRAY tell your doctor or pharmacist.

Things you must not do

Do not use AZEP NASAL SPRAY to treat any other complaints unless

your doctor or pharmacist tells you to.

Do not give AZEP NASAL SPRAY to anyone else, even if they have the same condition as you.

Things to be careful of

Make sure you know how you react to AZEP NASAL SPRAY before you drive, operate machinery, or do anything else that could be dangerous if you are tired, drowsy, dizzy or light-headed.

AZEP NASAL SPRAY is unlikely to make you feel drowsy. However, if you are drowsy, do not drive a car or operate machinery.

Be careful drinking alcohol while using AZEP NASAL SPRAY.

If you drink alcohol, any drowsiness may be worse.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using AZEP NASAL SPRAY.

Like other medicines, AZEP NASAL SPRAY may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- bleeding nose
- stinging or itching in nose
- sneezing
- bitter taste in mouth
- nausea
- headache

These side effects are usually mild and short-lived.

Drinking a flavoured drink a few minutes after using AZEP NASAL SPRAY may help remove any bitter taste.

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using AZEP NASAL SPRAY

Storage

Keep your AZEP NASAL SPRAY in a cool dry place where the temperature stays below 30°C.

Do not put AZEP NASAL SPRAY in the fridge.

Do not leave it in the car on hot days or on windowsills.

Heat can destroy some medicines.

Keep AZEP NASAL SPRAY where children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Do not use AZEP NASAL SPRAY for longer than 6 months after the bottle was first opened.

Disposal

If your doctor or pharmacist tells you to stop using AZEP NASAL SPRAY or the bottle has passed the expiry date, or the bottle has been open for longer than 6 months, ask your pharmacist what to do with any that is left over.

Product description

What it looks like

AZEP NASAL SPRAY is a clear, nearly colourless liquid in a brown glass bottle fitted with a spray pump and a cap.

The carton has tamper-evident seals.

Do not use if the seals over the carton ends are missing or broken.

The 5 mL bottle contains 35 metered sprays.

Ingredients

Active ingredients:

- azelastine hydrochloride, 0.1% w/v. [One spray contains 125 µg of azelastine (as hydrochloride)]

Other ingredients:

- hypromellose
- disodium edetate
- citric acid
- sodium chloride
- dibasic sodium phosphate dodecahydrate
- purified water

AZEP NASAL SPRAY does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

Mylan Health Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point, NSW 2000

Australia

www.mylan.com.au

Phone: 1800 314 527

This leaflet was prepared in March 2018.

AUST R 104853

Version 5

AZEP NASAL

SPRAY_cmi\mar18/00