

PACKAGE LEAFLET: INFORMATION FOR THE USER

Astepro 1mg/ml Nasal Spray Solution

Azelastine 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 any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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.
- In this leaflet Astepro 1 mg/ml Nasal Spray, Solution is called Astepro.

In this leaflet:

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

1. WHAT ASTEPRO IS AND WHAT IT IS USED FOR

Astepro contains azelastine hydrochloride which belongs to a group of medicines called antihistamines. Antihistamines work by preventing the effects of histamine that the body produces as part of an allergic reaction.

Astepro is used to treat allergic rhinitis in adults, adolescents and children 6 years and older. This is an allergic reaction to substances such as, for example, pollen, house dust mites or animal hair.

Usually it affects you by causing a runny nose, sneezing, itching or blocked nose. Astepro should help control these symptoms.

2. BEFORE YOU USE ASTEPRO

Do not use Astepro if

- if you are allergic (hypersensitive) to azelastine hydrochloride or any of the other ingredients of Astepro (see section 6).

If this applies to you, talk to your doctor or pharmacist.

Check with your doctor, or pharmacist before using Astepro

- if you are taking any other medicines obtained without a prescription

Using other medicines

Astepro is not known to be affected by other medicines.

Pregnancy and breast-feeding

There are only limited information on the effects of Astepro on the unborn or breast fed child.

If you are pregnant, trying to become pregnant or breast-feeding ask your doctor or pharmacist for advice

before using Astepro.

Driving and using machines

Astepro Nasal Spray has minor influence on the ability to drive and use machines.

Very rarely, you may experience fatigue or dizziness due to the disease itself or when using Astepro. In these cases, do not drive or operate machinery. Please be aware that drinking alcohol may enhance these effects.

3. HOW TO USE ASTEPRO

Always use Astepro exactly as your doctor has told you. Astepro is for nasal use.

Important:

If you are not sure of the correct dose or how to use this medicine, ask your doctor or pharmacist.

Adults and adolescents 12 years and older

- The recommended dose is two applications in each nostril twice daily. This dose should not be exceeded.

Children 6 to 11 years:

- One application in each nostril twice daily.

Astepro is not recommended for the use in children under 6 years of age due to a lack of data on safety and/or efficacy.

If possible, you should use Astepro regularly until your symptoms have disappeared. If you interrupt the use of Azelastine S your symptoms are likely to return.

Astepro is suitable for long-term use.

How to use the spray

1. Blow your nose first
2. Remove the protective cap (Diagram 1).
3. Before the first use, press the pump six times until an even spray emerges (Diagram 2). When Astepro Nasal Spray has not been used for three or more days, the pump must be pressed a sufficient number of times until a fine mist emerges.
4. Spray once into each nostril keeping head upright. Do not tilt head backwards (Diagram 3).
5. Wipe and replace the protective cap.



Diagram 1

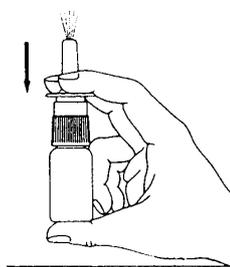


Diagram 2

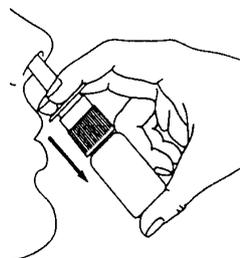


Diagram 3

If you use more Astepro than you should

If you spray too much Astepro into your nose you are unlikely to have any problems. If you are worried, contact your doctor.

If anyone, especially a child, accidentally drinks Astepro, contact your doctor or nearest hospital casualty department immediately.

If you forget to use Astepro

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

4. POSSIBLE SIDE EFFECTS

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

These effects include:

- Common (1 to 10 of 100 patients treated): An unpleasant taste in your mouth (especially if you tilt your head backwards when you are using the nasal spray).
- Uncommon (1 to 10 of 1,000 patients treated): Slight irritation of the inside of the nose (stinging, itching), sneezing and nose bleed.
- Rare (1 to 10 of 10,000 patients treated): The unpleasant taste might cause you to feel sick.
- Very rare (less than 1 of 10,000 patients treated): An allergic reaction, severe allergic reaction, rash, itching or nettlerash. Moreover, fatigue (weariness, exhaustion), dizziness weakness or a feeling of drowsiness can occur that may also be caused by the disease itself.

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.

5. HOW TO STORE ASTEPRO

Keep out of the reach and sight of children.

Do not use your spray after the expiry date given on the bottle label and the outer carton. The expiry date refers to the last day of the month.

Do not use longer than 6 months after first use.

Do not store the spray in the fridge or freezer.

Unused Medicines should not be disposed of via wastewater or household waste. Return any medicine you no longer need to your pharmacist.

6. FURTHER INFORMATION

What Astepro contains

The active substance is azelastine hydrochloride.

1 ml nasal spray contains 1 mg azelastine hydrochloride. Each squirt (0.14 ml) contains 0.14 mg azelastine hydrochloride equivalent to 0.13 mg azelastine.

The other ingredients are hypromellose, sucralose , liquid sorbitol (crystallising), disodium edetate, sodium citrate and purified water.

What Astepro looks like and contents of the pack

Astepro is a clear, colourless solution.

It comes in a brown glass bottle fitted with a spray pump. The 10 ml bottle contains 5 ml or 10 ml, the 20 ml bottle contains 17 ml, 20 ml or 22 ml fill volume of the nasal spray. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Meda Health Sales Ireland Limited,
Unit 34/35, Block A,
Dunboyne Business Park,
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Manufacturer

MEDA Pharma GmbH & Co. KG
Benzstrasse 1
61352 Bad Homburg
Germany

Or alternatively
MEDA Manufacturing GmbH,
Neurather Ring 1,
51063 Cologne,
Germany

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

UK: Rhinolast S 1 mg/ml, nasal spray, solution
AT: Allergodil mit Sucralose 1 mg/ml Nasenspray
DK: Allergodil Nasal
FI: Astepro 0.13 mg/annos nenäsumute, liuos
DE: Allergodil 1mg/ml Nasenspray, Lösung
IE: Astepro, 1 mg/ml Nasal Spray, Solution
ES: Aflun Sucralosa 1 mg/ml solución para
pulverización nasal
NL: Allergodil neusspray 1 mg/ml, neusspray
oplossing
PT: Allergodil BID 1 mg/ml Solução para
pulverização nasal
SE: Allergodil 0,13 mg/dos nässpray, lösning

This leaflet was last approved in **06/2014**