

**ASTEPRO ALLERGY- azelastine hcl spray, metered  
Bayer HealthCare LLC.**

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**Astepro Allergy**

**Drug Facts**

**Active ingredient**

Azelastine HCl 205.5 mcg (equivalent to 187.6 mcg azelastine)

**Purpose**

Antihistamine

**Uses**

**Uses**

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- nasal congestion
- runny nose
- sneezing
- itchy nose

**Warnings**

Only for use in the nose. Do not spray in eyes or mouth.

**Do not use** if you have ever had an allergic reaction to this product or any of its ingredients.

**Ask a doctor before use if you**

- have had recent nose ulcers or nose surgery
- have had a nose injury that has not healed

**When using this product**

- drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- you may get a bitter taste in your mouth. To help avoid this, tilt your head downward while spraying.
- nasal discomfort or sneezing may occur right after use
- do not share this bottle with anyone else as this may spread germs

**Stop use and ask a doctor if**

- an allergic reaction, such as a skin rash, to this product occurs
- you have severe or frequent nosebleeds

**If pregnant or breast-feeding,** ask a health professional before use.

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

## Directions

Read the User Guide for how to:

- prime the bottle before first use
- prime bottle again if not used for 3 or more days
- use the spray
- clean the spray nozzle if it gets clogged

adults and children 12 years and older	This product may be used either once or twice a day: <ul style="list-style-type: none"><li>• <u>once daily</u>: use 2 sprays in each nostril; <b>OR</b></li><li>• <u>twice daily</u>: use 1 or 2 sprays in each nostril every 12 hours</li><li>• <b>do not use more than 4 sprays</b> in each nostril in a 24 hour period</li></ul>
children 6 years to 11 years	<ul style="list-style-type: none"><li>• an adult should supervise use</li><li>• 1 spray in each nostril every 12 hours</li><li>• <b>do not use more than 2 sprays</b> in each nostril in a 24 hour period</li></ul>
children under 6 years	do not use

## Other information

### ***Other information***

- store between 20° to 25° C (68° to 77° F). Protect from freezing.
- keep this carton and the enclosed User Guide for important information
- do not use if tape printed with “sealed for your protection” on top and bottom carton flaps is not intact

### ***Inactive ingredients***

benzalkonium chloride, edetate disodium, hypromellose, purified water, sodium citrate, sorbitol, sucralose

## Questions or comments

### ***Questions or comments?***

1-800-317-2165 (Mon-Fri, 9AM-5PM EST)



VARIABLE PRINT  
 AREA  
 Printing Process: Ink Jet  
 - Lot & EXP: Printed On-line  
 - EXP Format: YYYY/MM

Azelastine HCl 205.5 mcg per spray  
 ANTIHISTAMINE NASAL SPRAY  
 FULL PRESCRIPTION STRENGTH  
 STEROID FREE  
 UP TO 24 HOUR RELIEF OF  
 Nasal congestion  
 Runny nose  
 Sneezing  
 Itchy nose

**ASTEPRO ALLERGY**  
 azelastine hcl spray, metered

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0280-0065
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**Route of Administration** NASAL

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>AZELASTINE HYDROCHLORIDE</b> (UNII: 0L591QR10I) (AZELASTINE - UNII:ZQI909440X)	AZ ELASTINE HYDROCHLORIDE	205.5 ug

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>WATER</b> (UNII: 059QF0KO0R)	

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:0280-0065-10	22 in 1 BOTTLE	07/05/2022	
1		1 in 1 CARTON; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
2	NDC:0280-0065-03	120 in 1 BOTTLE	07/05/2022	
2		3 in 1 PACKAGE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
3	NDC:0280-0065-01	60 in 1 BOTTLE	07/05/2022	
3		1 in 1 CARTON; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
4	NDC:0280-0065-02	120 in 1 BOTTLE	07/05/2022	
4		1 in 1 CARTON; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
5	NDC:0280-0065-04	200 in 1 BOTTLE	07/05/2022	
5		1 in 1 CARTON; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
6	NDC:0280-0065-09	120 in 1 BOTTLE	07/05/2022	
6		2 in 1 CARTON; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
7	NDC:0280-0065-05	22 in 1 BOTTLE	01/24/2023	
7		1 in 1 CARTON; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA213872	06/27/2022	

**Labeler** - Bayer HealthCare LLC. (112117283)

Revised: 9/2023

Bayer HealthCare LLC.