

AZELASTINE HCL- azelastine spray, metered
Amneal Pharmaceuticals NY LLC

Azelastine HCl Nasal Spray (205.5 mcg per spray)
Drug Facts

Active ingredient (in each spray)

Azelastine HCl 205.5 mcg (equivalent to 187.6 mcg azelastine)

Purpose

Antihistamine

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

- 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 motor vehicle or operation 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 (1-800-222-1222).

Directions

- Read the User Guide for how to:
 - prime the bottle before first use
 - use the spray
 - prime bottle again if not used for 3 or more days
 - clean the spray nozzle if it gets clogged

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

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 flaps is not intact

Inactive ingredients

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

Questions or Comments?

Call 1-877-835-5472 (Mon-Fri, 9AM-5PM EST)

Distributed by:

Amneal Pharmaceuticals LLC

Bridgewater, NJ 08807

Rev. 12-2021-00

User Guide

Azelastine HCl Nasal Spray (205.5 mcg per spray)

HOW TO START GETTING STEROID-FREE ALLERGY RELIEF RIGHT NOW

This User Guide will give you detailed directions on how to prime the bottle, use the spray, and how to clean a clogged nozzle.

Keep this User Guide as it contains important information.

**GET THE BOTTLE
READY**

Remove the dust cover over the tip of the bottle
and the white safety clip just under
the shoulders of the bottle before using.



PRIME THE BOTTLE

WHEN TO PRIME

- Before you use Azelastine HCl Nasal Spray for the first time
- If you have not used Azelastine HCl Nasal Spray for 3 or more days
- After you clean a clogged nozzle

HOW TO PRIME

- Aim bottle away from face.
- Hold bottle as shown and pump until a fine mist appears.
- If a fine mist does not appear after 6 sprays, your nozzle may be clogged. Please see “How to Clean a Clogged Nozzle” section.



HOW TO USE

Important: For use in your nose only

STEP 1

Blow your nose to clear your nostrils.

STEP 2

Tilt your head downward toward your toes.



STEP 3

Hold bottle with thumb under bottle and

spray nozzle between fingers.



STEP 4

Close one nostril.



**HOLD ONE
NOSTRIL SHUT**

STEP 5

Put the spray tip about $\frac{1}{4}$ inch to $\frac{1}{2}$ inch into the other nostril.
Hold bottle upright and aim the spray tip toward the back of your nose.

STEP 6

While sniffing gently, press the pump once or twice (according to dosing directions found in Table 1).

Repeat Steps 4, 5 and 6 in other nostril.

STEP 7

Do not tilt your head back immediately after using Azelastine HCl Nasal Spray. This will help to keep the medicine from going into your throat, which may cause a bitter taste.

STEP 8

When you finish using your Azelastine HCl Nasal Spray, wipe the spray tip with a clean tissue or cloth. Put the clip and cap back on the bottle.

FOR USE IN CHILDREN

An adult should supervise use.

(See Steps 1 through 8).

SELECT THE DOSE

DIRECTIONS

Do not use more than directed

TABLE 1

adults & children 12 years and older	This product may be used either once or twice a day: ■ once daily : use 2 sprays in each nostril; OR ■ twice daily : use 1 or 2 sprays in each nostril every 12 hours ■ do not use more than 4 sprays in each nostril in a 24 hour period
children 6 years to 11 years	■ an adult should supervise use ■ 1 spray in each nostril every 12 hours ■ do not use more than 2 sprays in each nostril in a 24 hour period
children under 6 years	do not use

IMPORTANT INFORMATION FOR USE

Remember, 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.

*In clinical trials, drowsiness was observed in less than 4% of patients taking Azelastine HCl Nasal Spray.

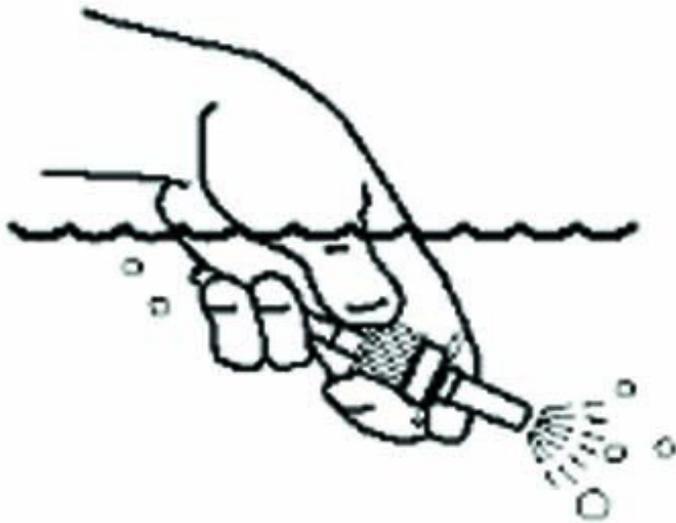
HOW TO CLEAN A CLOGGED NOZZLE

- If you cannot get your Azelastine HCl Nasal Spray to spray a fine mist, the nozzle may be clogged. Don't try to unclog the nozzle with a pin or sharp object—that can damage it.
- Unscrew the spray pump unit from the bottle by turning it to the left (counter-clockwise).



UNSCREW
PUMP UNIT

- **Keep open bottle out of reach of children.**
- Fill a bowl or container with warm water. Soak only the spray pump unit in the warm water. Pump the nozzle several times while holding it under the water to clear the clog.



**PUMP NOZZLE
WHILE HOLDING IT
UNDERWATER**

- Let the spray pump unit air dry before putting it back on.
- Tightly screw pump unit back on the open bottle by turning clockwise (to the right).
- After cleaning, follow the instructions for priming.

QUESTIONS OR COMMENTS?

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Rev. 12-2021-00

Principal Display Panel

Important: Read and keep the carton and User Guide for important information.

Children under 6 years: Do not use.

Keep out of reach of children.

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

Drowsiness may occur. Avoid alcoholic drinks. Alcohol, sedatives, and tranquilizers may increase drowsiness. Be careful when driving a motor vehicle or operating machinery.

Store upright between 20° to 25°C (68° to 77°F).

Protect from freezing.

Questions or comments? 1-877-835-5472

NDC 69238-2147-3

**Azelastine
Hydrochloride
Nasal Spray**

205.5 mcg per spray

Allergy

ANTIHISTAMINE NASAL SPRAY

200 Metered Sprays 1.01 fl oz (30 mL)

Distributed by:
**Amneal
Pharmaceuticals LLC**
Bridgewater, NJ 08807
Rev. 06-2023-00



LOT:
EXP:

**0.95" x 0.5"
Non-Varnish Area
For Lot & Exp**





AZELASTINE HCL

azelastine spray, metered

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69238-2147
Route of Administration	NASAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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AZELASTINE HYDROCHLORIDE (UNII: 0L591QR10I) (AZ ELASTINE - UNII:ZQI909440X)	AZ ELASTINE HYDROCHLORIDE	205.5 ug
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Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SORBITOL (UNII: 506T60A25R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69238-2147-3	200 in 1 BOTTLE	06/07/2024	
1		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
ANDA	ANDA216576	06/07/2024	

Labeler - Amneal Pharmaceuticals NY LLC (123797875)