

AZELASTINE HYDROCHLORIDE - azelastine hydrochloride spray, metered
Aurohealth LLC

Azelastine Hydrochloride Nasal Spray 205.5 mcg per spray

Drug Facts

Active ingredient (in each spray)

Azelastine hydrochloride USP 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 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 (1-800-222-1222) right away.

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	This product may be used either once or twice a day: <ul style="list-style-type: none"> ■ <u>once daily</u>: use 2 sprays in each nostril; OR ■ <u>twice daily</u>: 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 seal 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 (dihydrate), sorbitol and sucralose.

Questions or comments? 1-855-274-4122 (Monday – Friday 8:30 AM to 5:00 PM EST)

Distributed by:

AUROHEALTH LLC

279 Princeton-Hightstown Road
East Windsor, NJ 08520

Made in India

Code: AP/DRUGS/04/2016

User Guide

Azelastine Hydrochloride Nasal Spray 205.5 mcg per spray

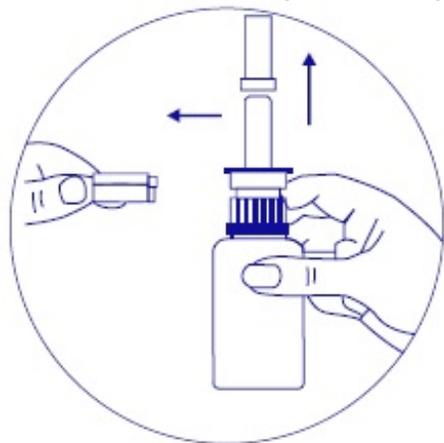
HOW TO START GETTING STEROID-FREE ALLERGY RELIEF RIGHT NOW

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 transparent cap and white clip before using.



PRIME THE BOTTLE

WHEN TO PRIME

- Before you use Azelastine Hydrochloride Nasal Spray for the first time
- If you have not used Azelastine Hydrochloride 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

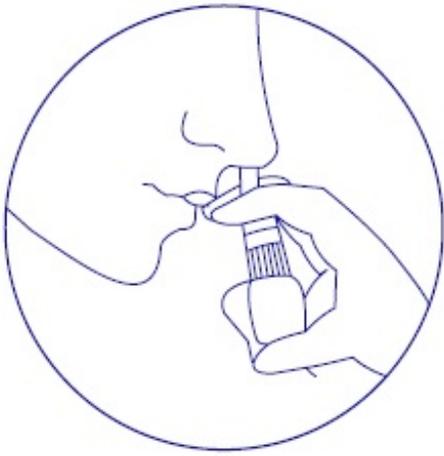
Important: For use in your nose only

STEP 1

Blow your nose to clear your nostrils.

STEP 2

Tilt your head downward toward your toes.



TILT HEAD DOWNWARD

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 Hydrochloride 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 Hydrochloride 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: ■ <u>once daily</u> : use 2 sprays in each nostril; OR ■ <u>twice daily</u> : 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:

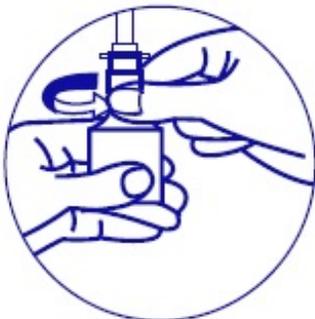
- Drowsiness may occur*
- › Avoid alcoholic drinks.
- › Alcohol, sedatives, and tranquilizers may increase drowsiness.
- › Be careful when driving a motor vehicle or operating machinery.

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

HOW TO CLEAN A CLOGGED NOZZLE

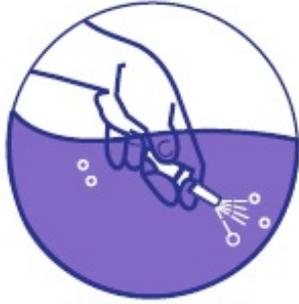
If you cannot get your Azelastine Hydrochloride Nasal Spray to spray a fine mist, the nozzle may be clogged. Don't try to unclog the nozzle with a pin or sharp object—that can damage it.

- 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? 1-855-274-4122 (Monday - Friday 8:30 AM to 5:00 PM EST)

Distributed by:

AUROHEALTH LLC

279 Princeton-Hightstown Road
East Windsor, NJ 08520

Made in India

Code: AP/DRUGS/04/2016

Revised: 01/2024

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - Container Label (11 mL Bottle)

AUROHEALTH

NDC 58602-020-51

Azelastine Hydrochloride

Nasal Spray

205.5 mcg per spray

ANTIHISTAMINE NASAL SPRAY

ALLERGY +

CONGESTION

60 METERED SPRAYS

0.37 fl oz (11 mL)

AUROHEALTH

NDC 58602-020-51

**Azelastine Hydrochloride
Nasal Spray**
205.5 mcg per spray

ANTI-HISTAMINE NASAL SPRAY

**ALLERGY +
CONGESTION**

60 METERED SPRAYS
0.37 fl oz (11 mL)

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 between 20° to 25°C (68° to 77°F). Protect from freezing.

Questions or comments? 1-855-274-4122
(Monday – Friday 8:30 AM to 5:00 PM EST)

Distributed by: **AUROHEALTH LLC**
279 Princeton-Hightstown Road
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Code: AP/DRUGS/04/2016

P 1437834

***Over Printing Zone**

Lot: XXXXXXXX

EXP: MM/YYYY

Prefix & Variables of Lot, EXP

shall be printed online during packing.

Coding Area

(27 x 12 mm)

Dotted lines not to be printed

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - Container Carton Label (11 mL Bottle)

AUROHEALTH

NDC 58602-020-51

***Compare to the active
ingredient in ASTEPRO® ALLERGY**

**Azelastine Hydrochloride
Nasal Spray
205.5 mcg per spray
ANTI-HISTAMINE NASAL SPRAY**

**ALLERGY +
CONGESTION**

FULL PRESCRIPTION STRENGTH

**STEROID FREE
Alcohol-Free
Fragrance-Free**

**UP TO
24 HOUR
RELIEF OF**

- **Nasal congestion**
- **Runny nose**
- **Sneezing**

- Itchy nose

60 METERED SPRAYS
0.37 fl oz (11 mL)

Azelastine Hydrochloride Nasal Spray
205.5 mcg per spray
 ALLERGY + CONGESTION

Azelastine Hydrochloride Nasal Spray
205.5 mcg per spray
 ANTIHISTAMINE NASAL SPRAY
 ALLERGY + CONGESTION

FULL PRESCRIPTION STRENGTH

UP TO 24 HOUR RELIEF OF

- Nasal congestion
- Runny nose
- Sneezing
- Itchy nose

60 METERED SPRAYS
0.37 fl oz (11 mL)

Drug Facts

Active ingredient (in each spray) Azelastine Hydrochloride USP 205.5 mcg (equivalent to 157.5 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 you

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

When using this product

- 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 stinging 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 (1-800-222-1222), right away.

Directions

- Read the User Guide for how to:
- prime the bottle before first use
- use the spray

Drug Facts (continued)

- 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

- use **daily**, use 2 sprays in each nostril. OR
- use **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

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 seal printed with "sealed for your protection" on top and bottom carton flaps is not intact.

Inactive ingredients benzalkonium chloride, edetate disodium, hydroxyethylcellulose, purified water, sodium chloride (halo-saline), sorbitol and xanthan.

Questions or comments? 1-866-274-4122 (Monday - Friday 8:30 AM to 5:00 PM EST)

*This product is not manufactured or distributed by Bayer HealthCare LLC, distributor of STEPPO® ALLERGY

Distributed by:
 AUROHEALTH LLC
 279 Pennington-Highstown Road
 East Windsor, NJ 08820
 Made in India
 Code: AP0RUGS042016

INDOOR & OUTDOOR
 Allergy Relief

sealed for your protection

P1062631

Unvarnished Zone (dotted line not for printing) 67 x 20 mm

UNVARNISHED ZONE (see seal for printing)

* Lot: XXXXXXXXXX
 EXP: MM/YYYY
 Prefix & Variables of Lot, EXP shall be printed online during packing.

AZELASTINE HYDROCHLORIDE

azelastine hydrochloride spray, metered

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58602-020
Route of Administration	NASAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
HYPROMELLOSE 2910 (4000 MPA.S) (UNII: RN3152OP35)	
WATER (UNII: 059QF0KO0R)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	WHITE (clear colorless)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-020-51	1 in 1 CARTON	01/27/2025	
1		60 in 1 BOTTLE, SPRAY; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
2	NDC:58602-020-52	1 in 1 CARTON	01/27/2025	
2		120 in 1 BOTTLE, SPRAY; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
3	NDC:58602-020-07	1 in 1 CARTON	01/27/2025	
3		200 in 1 BOTTLE, SPRAY; 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	ANDA216561	01/27/2025	

Labeler - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650918514	ANALYSIS(58602-020) , MANUFACTURE(58602-020)