

**AZELASTINE HYDROCHLORIDE- azelastine hydrochloride spray, metered**  
**Walgreens**

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**Drug Facts**

**Active ingredient (in each spray)**

Azelastine hydrochloride 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
- runny nose
- 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 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
  - 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"><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**

- store between 20°C to 25°C (68°F to 77°F). Protect from freezing.
- keep this carton and the enclosed User Guide for important information
- do not use if sealed package is torn or opened

**Inactive ingredients**

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

**Questions or comments?**

call toll free **1-800-706-5575**, weekdays, 8:30am – 5:00pm Eastern Standard Time

**Principal Display Panel - Bottle**

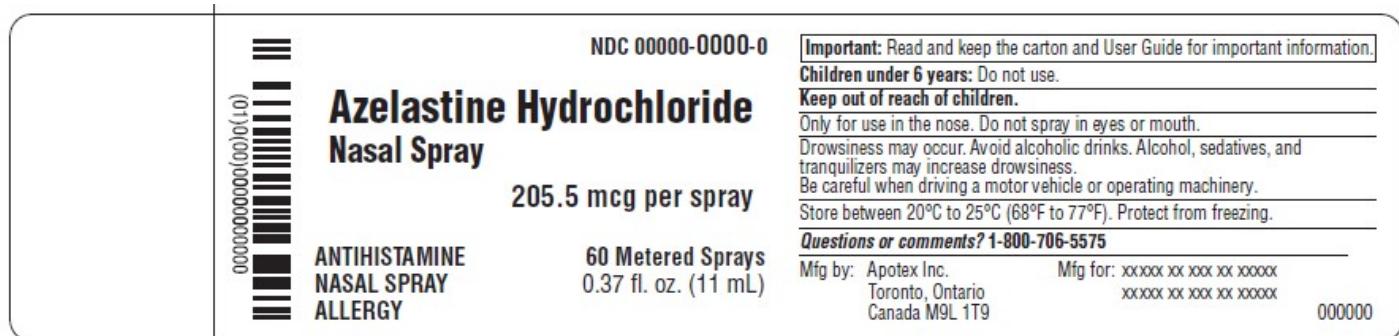
Bottle LABEL - PRINCIPAL DISPLAY PANEL

NDC 0363-0653-01

Azelastine Hydrochloride Nasal Spray (205.5 mcg per spray)

ANTIHISTAMINE NASAL SPRAY

60 Metered Sprays



**Principal Display Panel - Carton**

CARTON LABEL - PRINCIPAL DISPLAY PANEL

NDC 0363-0653-03

Azelastine Hydrochloride Nasal Spray (205.5 mcg per spray)

60 Metered Sprays

ANTIHISTAMINE NASAL SPRAY

24 Hour Relief of:

- Nasal congestion
- Runny nose
- Sneezing
- Itchy nose



## Principal Display Panel - Bottle

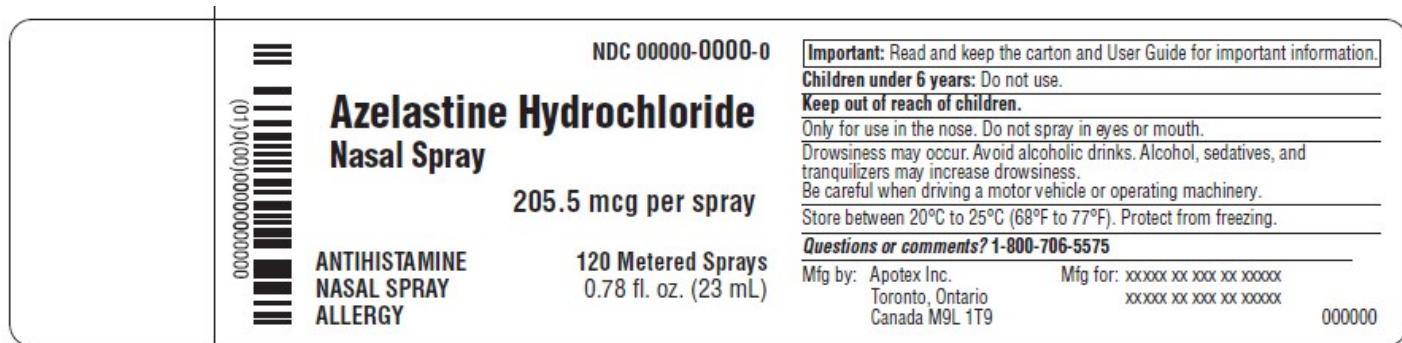
Bottle LABEL - PRINCIPAL DISPLAY PANEL

NDC 0363-0653-02

Azelastine Hydrochloride Nasal Spray (205.5 mcg per spray)

ANTIHISTAMINE NASAL SPRAY

120 Metered Sprays



## Principal Display Panel - Carton

### CARTON LABEL - PRINCIPAL DISPLAY PANEL

NDC 0363-0653-04

Azelastine Hydrochloride Nasal Spray (205.5 mcg per spray)

120 Metered Sprays

### ANTIHISTAMINE NASAL SPRAY

24 Hour Relief of:

- Nasal congestion
- Runny nose
- Sneezing
- Itchy nose



# AZELASTINE HYDROCHLORIDE

azelastine hydrochloride spray, metered

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-0653
Route of Administration	NASAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
EDETALE DISODIUM (UNII: 7FLD91C86K)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-0653-03	1 in 1 CARTON	06/25/2024	
1	NDC:0363-0653-01	60 in 1 BOTTLE, SPRAY; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
2	NDC:0363-0653-04	1 in 1 CARTON	06/25/2024	
2	NDC:0363-0653-02	120 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	ANDA216421	06/25/2024	

**Labeler** - Walgreens (008965063)

**Registrant** - Apotex Inc. (209429182)

## **Establishment**

Name	Address	ID/FEI	Business Operations
Apotex Inc.		255092496	analysis(0363-0653) , manufacture(0363-0653)

Revised: 5/2024

Walgreens