AZELASTINE HYDROCHLORIDE- azelastine hydrochloride spray, metered
Walgreens

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: • 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

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

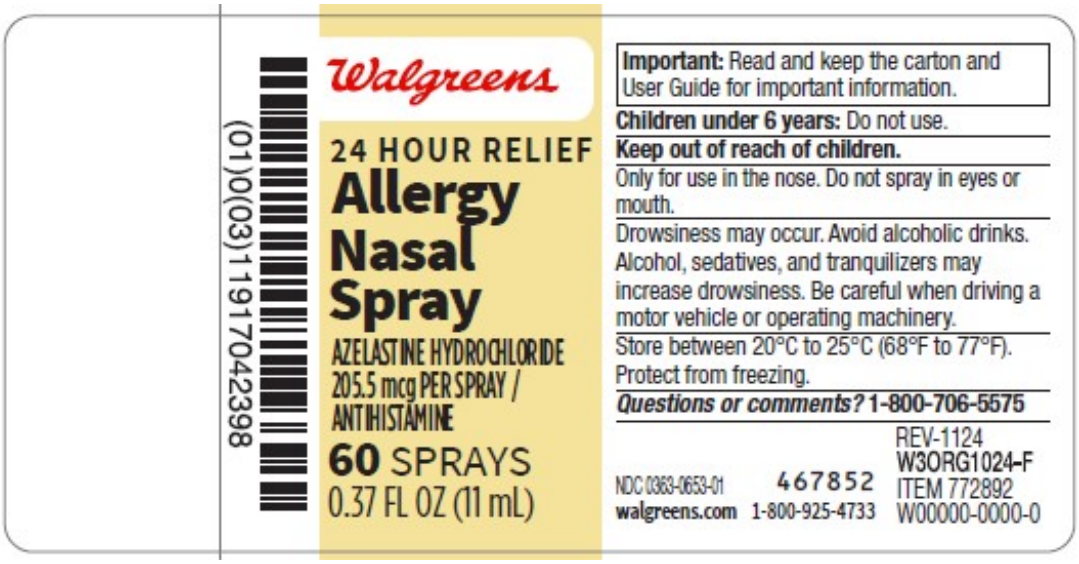
Bottle LABEL - PRINCIPAL DISPLAY PANEL

NDC 0363-0653-01

Azelastine Hydrpchloride 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

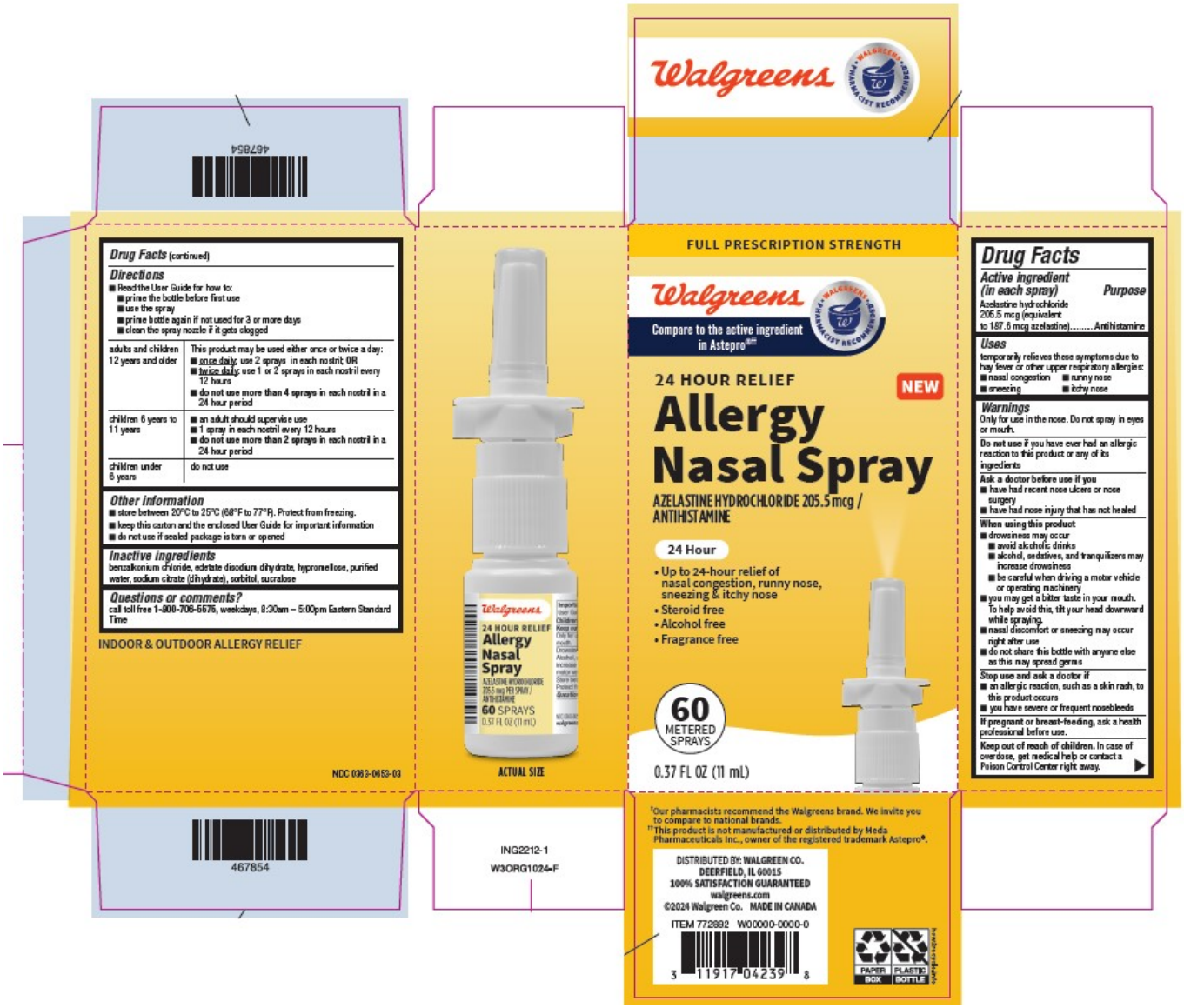
Azelastine Hydrochloride Nasal Spray (205.5 mcg per spray)

60 Metered Sprays

ANTIHISTAMINE NASAL SPRAY

24 Hour Relief of:

- Nasal congestion
- Runny nose
- Sneezing
- Itchy nose



Principal Display Panel - Bottle

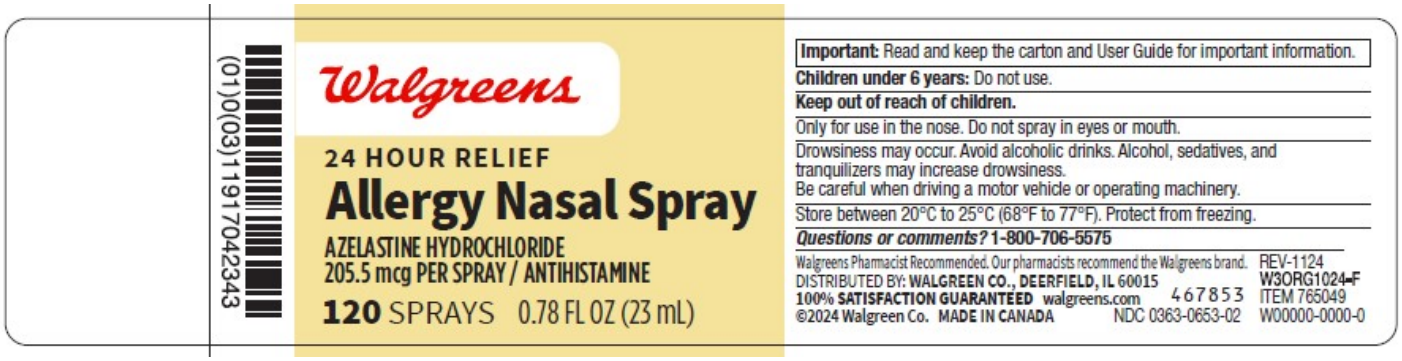
Bottle LABEL - PRINCIPAL DISPLAY PANEL

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

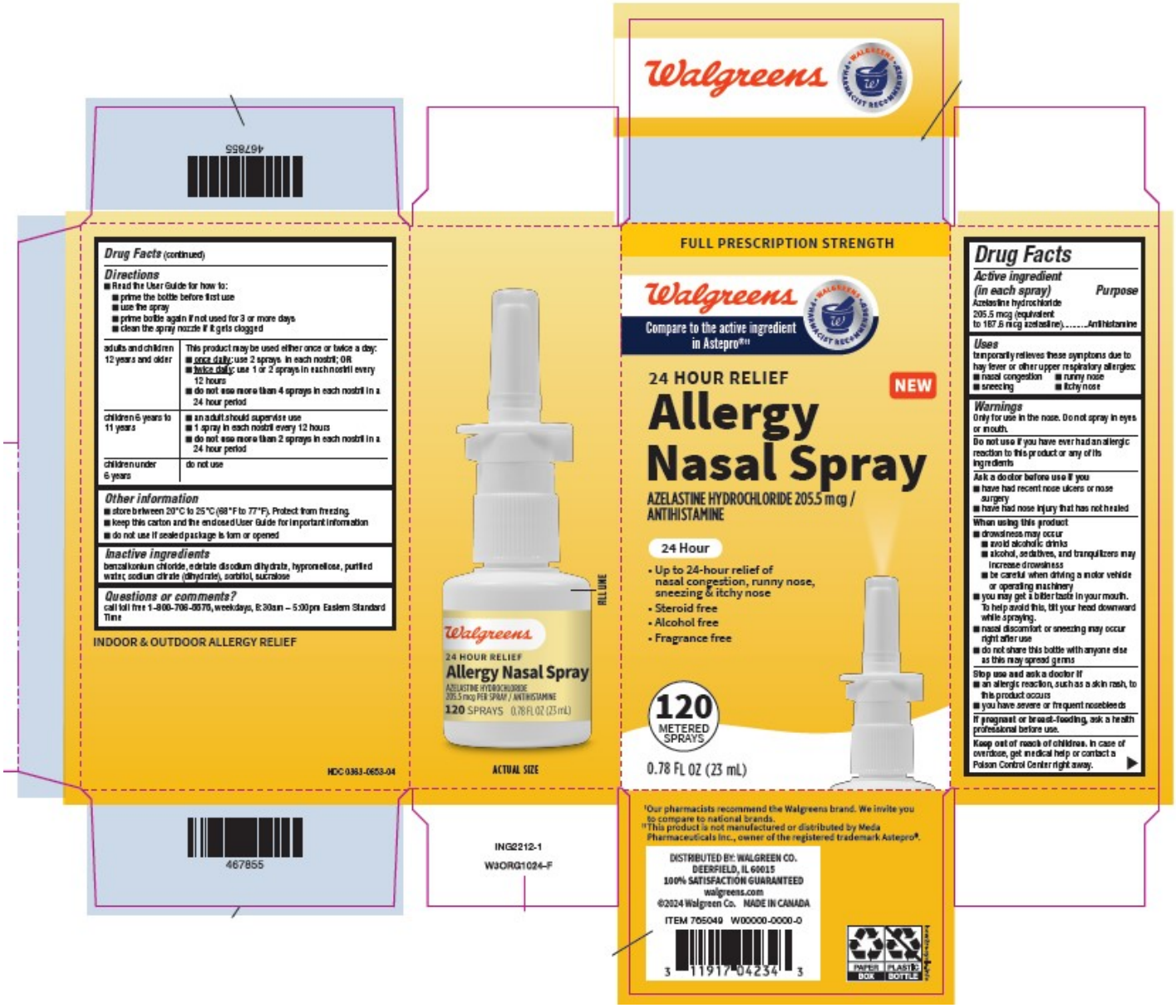
Azelastine Hydrochloride Nasal Spray (205.5 mcg per spray)

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)	
EDETATE 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	07/01/2025	
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	07/01/2025	
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	07/01/2025	

Labeler - Walgreens (008965063)

Revised: 5/2025 Walgreens