

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

213872Orig1s000

LABELING









Drug Facts (continued)
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?
1-800-317-2165 (Mon-Fri, 9AM-5PM EST)

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Whippany, NJ 07981
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Product of Germany.
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INDOOR & OUTDOOR
Allergy Relief

NDC 0280-0065-01

ASTEPRO® ALLERGY

First Antihistamine Nasal Spray FDA-Approved for Over-the-Counter Use

ASTEPRO® ALLERGY

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



60 METERED SPRAYS
0.37 fl oz (11 mL)

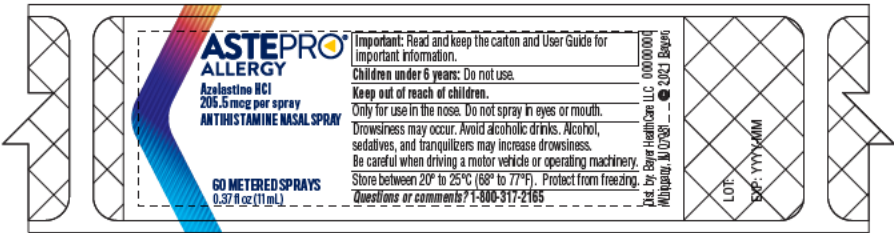
Alcohol-Free
Fragrance-Free



LOT:
EXP:YYYY-MM



Drug Facts	
Active ingredient (in each spray)	Purpose
Azelastine HCl 205.5 mcg (equivalent to 187.6 mcg azelastine)	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 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	



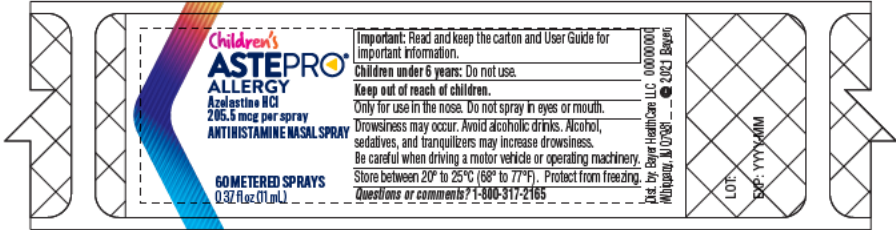




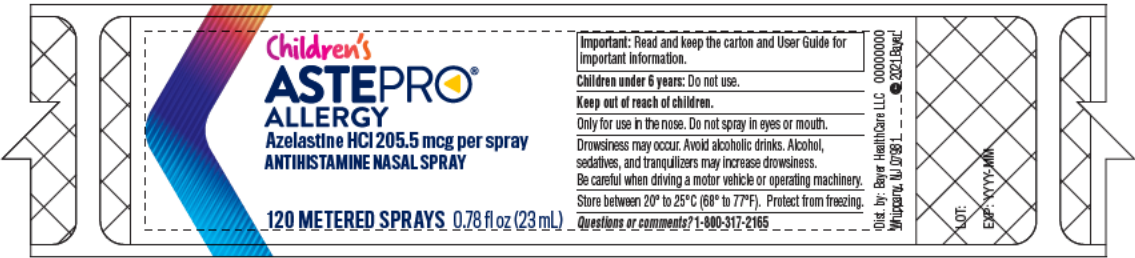
















ASTEPRO[®]

ALLERGY

STERIOD
FREE

First Antihistamine Nasal Spray FDA-Approved for Over-the-Counter Use

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children under 6 years	do not use
Other information ■ store between 20° to 25°C (68° to 77°F). Protect from freezing. ■ keep this label and the enclosed User Guide for important information ■ do not use if sealed package is torn or opened	
Inactive ingredients benzalkonium chloride, edetate disodium, hypromellose, purified water, sodium citrate, sorbitol, sucralose	
Questions or comments? 1-800-317-2165 (Mon–Fri, 9AM–5PM EST)	

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LOT:
EXP: YYYY-MM

NDC 0280-0065-03





Actual Size 100%

FDA00342-1

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/s/

NUSHIN F TODD
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