

**ASSURED SEVERE CONGESTION NASAL RELIEF- oxymetazoline hydrochloride spray
Greenbrier International, Inc**

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Assured Nasal Spray Severe Congestion 0.5 oz (21528, 2019) DZ

Active ingredient	Purpose
Oxymetazoline HCL 0.05%.....	Nasal decongestant

Uses

temporarily relieves nasal congestion due to:

- common cold
- hay fever
- upper respiratory allergies
- temporarily relieves sinus congestion and pressure
- shrinks swollen nasal membranes so you can breathe more freely

Warnings

Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland

When using this product

- do not use more than directed
- do not use for more than 3 days. Use only as directed. Frequent or prolonged use may cause nasal congestion to recur or worsen.
- temporary discomfort such as burning, stinging, sneezing, or an increase in nasal discharge may occur
- use of this container by more than one person may spread infection.

Stop use and ask a doctor if symptoms persist

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- adults and children 6 to 12 years of age (with adult supervision): 2 or 3 sprays in each nostril not more than every 10 to 12 hours. Do not exceed 2 doses in any 24-hour period.
- children under 6 years of age: ask a doctor.

Shake well before use. Remove safety seal. To open, rotate cap to align the marks. Squeeze cap on both sides in a counter-clockwise turn and pull off to remove. To spray, remove clamp and hold bottle with thumb at base and nozzle between first and second fingers. Without tilting the head, insert nozzle into nostril. Fully depress rim with a firm, even stroke and sniff deeply. Wipe nozzle clean after use and snap cap back onto the bottle.

Other information

- store at room temperature 20° and 25°C (68° to 77°F)

Inactive ingredients

benzalkonium chloride, benzyl alcohol, camphor edetate disodium, eucalyptol, menthol, polysorbate 80, propylene glycol, purified water, sodium phosphate dibasic, sodium phosphate, monobasic monohydrate

Distributed by:

Greenbrier International, Inc.

500 Volvo Parkway

Chesapeake, VA 23320

Made in China

ASSURED

SEVERE CONGESTION

Nasal Relief

• Oxymetazoline HCl 0.05%
(Nasal Decongestant)

COMPARE TO AFRIN® SEVERE
CONGESTION NASAL SPRAY*
ACTIVE INGREDIENT

CHILD SAFETY CAP

ASSURED

SEVERE CONGESTION

Nasal Relief

• Oxymetazoline HCl 0.05%
(Nasal Decongestant)

**Pump Mist
Anti-Drip**

- **Maximum Strength with Menthol**
- **Fast, Powerful Congestion Relief**
- **12 Hour Relief**

**12
HOUR
RELIEF**

**0.5 FL OZ
(15 ML)**



Drug Facts (continued)

Other information

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Inactive ingredients

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Questions or comments?

Call 1-888-645-8204

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

TAMPER EVIDENT: DO NOT USE IF PRINTED SEAL AROUND PUMP AND CAP IS BROKEN OR MISSING.

*This product is not manufactured or distributed by Bayer®, distributor of Afrin® Severe Congestion Nasal Spray.

228646

DISTRIBUTED BY:
**GREENBRIER
INTERNATIONAL, INC.
500 VOLVO PARKWAY
CHESAPEAKE, VA 23320**

Made in China

21528-ZDP-BX-R1
NAS-MD-ZDP101-R2



ASSURED

SEVERE CONGESTION

Assured™ Nasal Relief Spray Pump Mist Anti-Drip uses a special formulation that prevents dripping from your nose and down your throat. Our extra strength formulation works almost instantly and will last 12 hours for your nasal relief.



DIRECTIONS FOR USE:

STEP 1: To open, rotate cap to align the marks. Squeeze cap on both sides in a counter-clockwise turn and pull off to remove. To spray, remove clamp.

STEP 2: Use as directed.

STEP 3: Wipe nozzle clean after use, and snap cap back onto the bottle.

Full directions in drug facts panel

Drug Facts

Active ingredient

Oxymetazoline hydrochloride 0.05%.....Nasal decongestant

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Directions

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- children under 6 years of age: consult a doctor
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Lot#:

Exp:

ASSURED SEVERE CONGESTION NASAL RELIEF

oxymetazoline hydrochloride spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:33992-5284	
Route of Administration	NASAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
OXYMETAZOLINE HYDROCHLORIDE (UNII: K89MJ0S5VY) (OXYMETAZOLINE - UNII:8VLN5B44ZY)		OXYMETAZOLINE HYDROCHLORIDE	0.2 mg in 0.4 mL	
Inactive Ingredients				
Ingredient Name			Strength	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)				
BENZYL ALCOHOL (UNII: LKG8494WBH)				
SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM (UNII: GR686LBA74)				
EDETATE DISODIUM (UNII: 7FLD91C86K)				
WATER (UNII: 059QF0KO0R)				
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)				
EUCALYPTOL (UNII: RV6J6604TK)				
MENTHOL (UNII: L7T10EP3A)				
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN)				
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:33992-5284-5	1 in 1 BOX	11/03/2016	
1		15 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	05/14/2015		

Labeler - Greenbrier International, Inc (610322518)

Revised: 5/2019

Greenbrier International, Inc