ASSURED NASAL RELIEF- oxymetazoline hydrochloride spray
United Exchange Corp.

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.

Active ingredient **Purpose**

Oxymetazoline HCl.....Nasal decongestant

Uses

temporarily relieves nasal congestion due to:

- common cold
- hay fever
- upper respiratory allergies
- temprarily relievves 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 urinated due to an enlarged prostate gland

When using this product

- **do not use more than directed**
- do not use 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 often than every 10 to 12 hours. Do not exceed 2 doses in any 24-hour period.
- children under 8 years of age: ask a doctor.

Shake well before use. 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 tiliting 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 between 20and 25°C (68° and 77°F)

- retain carton for future reference on full labeling

Inactive ingredients benzalkonium chloride, benzyl alcohol, dibasic sodium phosphate, disodium EDTA, distilled water, monobasic sodium phosphate, PEG 1450, PVP K30

Distributed by:

Greenbrier International, Inc.

500 Volvo Parkway

Chesapeake, VA 23320

Made in Korea

ASSURED™

ORIGINAL

Nasal Relief Spray

SAFETY SEALED: Do not use if printed seal on bottle is broken or missing

COMPARE TO ACTIVE INGREDIENT IN AFRIN® ORIGINAL*

Drug Facts

Active ingredient — **Purpose**

Oxymetazoline HCl 0.05%.....Nasal decongestant

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  - hay fever
  - upper respiratory allergies
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LOT:
EXP:

ASSURED™

ORIGINAL

Nasal Relief Spray

Pump Mist

Anti-Drip

Drug Facts (continued)

Other information

- store between 20° to 25°C (68° to 77°F)
- retain carton for future reference on full labeling

Inactive ingredients

benzalkonium chloride, benzyl alcohol, dibasic sodium phosphate hydrate, disodium EDTA, distilled water, monobasic sodium phosphate dihydrate, PEG 1450, PVP K30

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ASSURED™

ORIGINAL

Nasal Relief Spray

Pump Mist

Anti-Drip

• Oxymetazoline HCl-
Nasal Decongestant

Rapid & Powerful Congestion Relief

12 Hour Relief

12 HOUR RELIEF

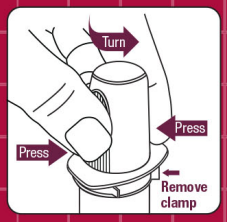
NET WT
0.5 FL OZ (15 mL)

ASSURED™

ORIGINAL

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.

Full directions in drug facts panel



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

Made in Korea

*This product is not manufactured or distributed by Bayer, owner of the registered trademark Afrin® Original.

ASSURED NASAL RELIEF

oxymetazoline hydrochloride spray

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:65923-387
Route of Administration	NASAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OXYMETAZOLINE HYDROCHLORIDE (UNII: K89MJ0S5VY) (OXYMETAZOLINE - UNII:8VLN5B44ZY)	OXYMETAZOLINE HYDROCHLORIDE	0.05 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
SODIUM PHOSPHATE, DIBASIC DIHYDRATE (UNII: 94255I6E2T)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
WATER (UNII: 059QF0KO0R)	
SODIUM PHOSPHATE, MONOBASIC, DIHYDRATE (UNII: 5QWK665956)	
POLYETHYLENE GLYCOL 1450 (UNII: OJ4Z5Z32L4)	
POVIDONE K30 (UNII: U725QWY32X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65923-387-05	1 in 1 BOX	10/05/2016	
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	11/20/2013	

Labeler - United Exchange Corp. (840130579)

Revised: 10/2016 United Exchange Corp.