ASSURED 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.

Drug Facts

Active ingredient Purpose

Oxymetazoline HCl......Nasal decongestant

Uses

- temporarily relieves nasal congestion due to:
- common cold
- hay fever
- upper respiratory allergies
- sinusitis
- 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. To spray, hold bottle with thumb at base and nozzle between first and second fingers. Without tilting head, insert nozzle into nostril. Fully depress rim with a firm, even stroke and sniff deeply. Wipe nozzle clean after use.

Other information

- store between 15° and 25°C (59° 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



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PUMP MIST ANTI-DRIP ORIGINAL

Oxymetazoline HCI-Nasal Decongestant

Features:

- Fast, Powerful **Congestion Relief**
- 12 Hour Relief



ASSURED; PUMP MIST ANTI-DRIP

ORIGINAL

Oxymetazoline HCI-Nasal Decongestant



PUMP MIST ANTI-DRIP ORIGINAL

Oxymetazoline HCI-Nasal Decongestant

Assured Nasal Relief Anti-Drip Pump Mist is 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.

Parkway ske. VA 23320

LOT & EXP.

ASSURED NASAL RELIEF

oxymetazoline hydrochloride spray

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:33992-8685

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

Inactive Ingredients			
Ingredient Name	Strength		
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7)			
BENZYL ALCOHOL (UNII: LKG8494WBH)			
SO DIUM PHO SPHATE, DIBASIC (UNII: GR686LBA74)			
EDETATE DISO DIUM (UNII: 7FLD91C86K)			
WATER (UNII: 059QF0KO0R)			
SODIUM PHO SPHATE, MO NO BASIC (UNII: 3980 JIH2SW)			
POLYETHYLENE GLYCOL 1450 (UNII: OJ4Z5Z32L4)			
PO VIDO NE K30 (UNII: U725QWY32X)			

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:33992-8685-1	1 in 1 TUBE				
1		30 mL in 1 BOTTLE				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	04/30/2013		

$\boldsymbol{Labeler} \text{ - } \textbf{Greenbrier International, Inc. (610322518)}$

Revised: 4/2013 Greenbrier International, Inc.