NO DRIP SEVERE CONGESTION PREMIER VALUE- oxymetazoline hcl nasal solution spray Chain Drug Consortium

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.

Nas al Spray

Active Ingredient

Oxymetazoline hydrochloride 0.05%

$\square Purpose$

Nasal Decongestant

Uses

- Temporarily relieves nasal congestion due to:
 - o Common cold
 - Hay fever
 - Upper respiratory allergies
- Shrinks swollen nasal membranes so you can breathe more freely

Warnings

Ask a doctor before use if you have

- heart disease
- high blood pressure
- diabetes
- thyroid disease
- 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 often than every 10 to 12 hours. Do not exceed 2 doses within any 24-hour period.
- **Children under 6 years of age:** Ask a doctor.

Shake well before use. Before using for the first time remove the protective cap from the tip and prime metered pump by depressing pump firmly several times. 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 each use.

Other Information

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

Inactive Ingredients

Benzalkonium Chloride, Benzyl Alcohol, Camphor, Edetate Disodium, Eucalyptol, Menthol, Microcrystalline Cellulose, Carboxymethylcellulose Sodium, Polyethylene Glycol, Povidone, Sodium Phosphate Dibasic, Sodium Phosphate Monobasic, Water.

Additional information listed on other panels

SAFETY SEALED: DO NOT USE IF IMPRINTED SEAL ON BOTTLE IS BROKEN OR MISSING.

*This product is not manufactured or distributed by Procter & Gamble, distributor of Vicks Sinex.

Distributed By:

Chain Drug Consortium

3301 NW Boca Raton Blvd, Suite 101

Boca Raton, FL 33431

Made in USA

If for any reason you are not satisfied with this product, please return it to the store where purchased for a full refund.

Principal Display

*Compare to the active ingredient in Afrin

Premier Value

Nasal Decongestant

No Drip

ISEVERE CONGESTION

INASAL SPRAY I

Oxymetazoline HCl Nasal Solution

12 HOUR PUMP MIST

Fast, Powerful Congestion Relief

- Colds
- Allergies

Maximum

Strength

plus Menthol

1 FL OZ (30 mL)



NO DRIP SEVERE CONGESTION PREMIER VALUE

oxymetazoline hcl nasal solution spray

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68016-309
Route of Administration	NASAL		

l	Active Ingredient/Active Moiety			
ı	Ingredient Name	Basis of Strength	Strength	
	O XYMETAZO LINE HYDRO CHLO RIDE (UNII: K89 MJ0 S5VY) (O XYMETAZO LINE - UNII: 8 VLN5B44ZY)	OXYMETAZOLINE HYDROCHLORIDE	0.05 mg in 1 mL	

Inactive Ingredients	
Ingredient Name	Strength
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)	
EUCALYPTOL (UNII: RV6J6604TK)	
MENTHOL (UNII: L7T10EIP3A)	
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)	
CARBOXYMETHYLCELLULOSE (UNII: 05JZI7B19X)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
PO VIDO NE (UNII: FZ989GH94E)	
SODIUM PHO SPHATE, DIBASIC, ANHYDRO US (UNII: 22ADO53M6F)	
SODIUM PHO SPHATE, MO NO BASIC, ANHYDRO US (UNII: KH7I0 4HPUU)	
WATER (UNII: 059QF0KO0R)	

Packaging			
# Item Co	de Package Description	Marketing Start Date	Marketing End Date
1 NDC:68016-3	1 in 1 CARTON		
1	30 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	11/0 4/20 14		

Labeler - Chain Drug Consortium (101668460)

Registrant - Product Quest Mfg (927768135)

Establishment				
Name	Address	ID/FEI	Business Operations	
Product Quest Mfg		927768135	manufacture(68016-309)	

Revised: 10/2015 Chain Drug Consortium