NO DRIP NASAL MIST- oxymetazoline spray liquid CVS Health

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

Oxymetazoline Hydrochloride 0.05%

Purpose

Nasal Decongestant

Uses

Temporarily relieves nasal congestion due to:

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

Warnings

Ask a Doctor before use if you have

- heart diease
- high blood pressure
- diabetes
- thyiod diease
- trouble urinating due to enlarged rostate gland.

When using this product

- Do not use more than directed
- do not use for more than three 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 the reach of children

if swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Before using for the first time, remove the protective cap form the tip and prime the 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 nostrile. Fully depress rim with a firm and even stroke, and sniff deeply.
- Wipe nozzle clean after use.
- Adults and children 6 to under 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 consult a doctor.

Other information

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

Inactive Ingredients

Benzalkonium Chloride Solution, Benzyl Alcohol, Edetate Disodium, Flavor, Glycerin, Microcrystalline Cellulose and Carboxymethylcellulose Sodium, Polyethylene Glycol, Povidone, Purified Water, Sodium Phosphate Dibasic, Sodium Phosphate Monobasic

Principal Panel 0.5 FLOZ Bottle



CVS Health No Drip Nasal Mist

Extra Moisturizing

Nasal Spray

Oxymetazoline HCL 0.05%

12 hour Nasal Spray

Net Wt 0.5 FLOZ (15ml)







SEE CARTON FOR FULL LABELING DO NOT USE IF PRINTED SEAL OVER

CAP IS TORN OR MISSING Active ingredient

Oxymetazoline hydrochloride 0.05% Uses • See Carton

When using this product • do not use more urinating due to an enlarged prostate gland. person may spread infection. Stop use and Warnings Ask a doctor before use if you have • heart disease • high blood pressure than directed • do not use for more than 3 prolonged use may cause nasal congestion to recur or worsen. . temporary discomfort such as burning, stinging, sneezing or an use of this container by more than one days. Use only as directed. Frequent or increase in nasal discharge may occur thyroid disease • diabetes • trouble

If pregnant or breast-feeding, ask a health after use. • adults and children 6 to under 12 every 10 to 12 hours. Do not exceed 2 doses professional before use. Keep out of reach years of age (with adult supervision): 2 or 3 iof children. If swallowed, get medical help away. Directions To use: squeeze cap at sprays in each nostril not more often than in any 24-hour period. • children under 6 counterclockwise to remove. Secure cap or contact a Poison Control Center right base on opposite sides and twist cap ask a doctor if symptoms persist. years of age: ask a doctor.

Distributed by: CVS Pharmacy, Inc. One CVS Drive, Woonsocket, RI 02895 © 2018 CVS/pharmacy OVS.com® 1-800-SHOP CVS

Made in the U.S.A. of U.S. and imported ingredients and components V-34744 7908073

Principal display panel- Carton label



Health. **SAD**♠

DO NOT USE IF PRINTED SEAL OVER CAP IS TORN OR MISSING

Drug Facts

Active ingredient

Purpose ymetacoline hydrochloride 0.05%... Nassil decongestant

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Drug Facts (controll) Other Information

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To reapply cap, turn cap on pump clockwise until it locks.

"This product is not manufactured or distributed by Bayer HeathCare LLC, the distributor of Afrin" No Drip Extra Moisturizing Pump Mist.

IMPORTANT: KEEP OUTER CARTON FOR FUTURE REFERENCE ON FULL LABELING

PCVS Health.

Compare to the active ingredient in Afrin[®] No Orip Extra Moisturizing Pump Mist*

Extra Moisture

No Drip

Nasal **(2)** Mist

OXYMETAZOLINE

HCI 0.05% Nasal decongestant 12 HOUR PUMP MIST

- Soothes and helps rehydrate dry noses
- Fast & effective congestion relief



Actual Bottle Size on Side Panel

0.5 FL 0Z (15 mL) Distributed by: CVS Pharmacy, Inc. One CVS Drive Woonsocket, FE 00995 0 2018 CVS-bharmach 0 2018 CV

Made in the U.S.A. of U.S. and imported ingredients and components V-34744 CVS Quality

Package Contains One Bottle

Actual Size

LOT



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Extra Moisturizing

Nasal Spray

Oxymetazoline HCL 0.05%

12 hour Nasal Spray

Net Wt 0.5 FLOZ (15ml)



NO DRIP NASAL MIST

oxymetazoline spray liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-312	
Route of Administration	NASAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OXYMETAZOLINE HYDROCHLORIDE (UNII: K89MJ0S5VY) (OXYMETAZOLINE - UNII:8 VLN5B44ZY)	OXYMETAZOLINE HYDROCHLORIDE	50 mg in 100 mL	

Inactive Ingredients	
Ingredient Name	Strength
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)	
SODIUM PHO SPHATE, MO NO BASIC (UNII: 3980 JIH2SW)	
SO DIUM PHO SPHATE, DIBASIC (UNII: GR686LBA74)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7)	
WATER (UNII: 059QF0KO0R)	
PO VIDO NE (UNII: FZ989 GH94E)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:69842-312- 51	1 in 1 CARTON	08/30/2018		
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	08/30/2018		

Labeler - CVS Health (062312574)

Registrant - Sheffield Pharmaceuticals LLC (151177797)

Establishment				
Name	Address	ID/FEI	Business Operations	
Sheffield Pharmaceutical LLC		151177797	manufacture(69842-312)	

Revised: 10/2018 CVS Health