CVS HEALTH ULTRA FINE MIST- oxymetazoline hydrochloride spray CVS PHARMACY, 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.

CVS Health™ Sinus Relief Drug Facts

Active ingredient

Oxymetazoline hydrochloride 0.05%

Purpose

Nasal Decongestant

Uses

temporarily relieves

- nasal congestion due to a cold, heavy fever, or other upper respiratory allergies
- Sinus congestion and pressure

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 exceed recommended dosage
- do not use this product 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 at (1-800-222-1222).

Directions

- **adults & children 6 years & older (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 2 to under 6 years:** ask a doctor
- Children 2 years: ask a doctor

Shake well before use. Before using the first time, remove the protective cap from the tip by pressing and twisting off the cap. Rotate the lock tab to align arrow marks to unlock the pump. 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 titling head, insert nozzle into nostril. Fully depress rim with a firm, even stroke and sniff deeply. Wipe nozzle clean after use. Lock the pump by ensuring that arrow marks are not aligned and replace the protective cap on tip.

Other information

store at room temperature

Inactive ingredients

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

Questions or comments?

1-866-467-2748

Principal Display Panel

CVS Health™

Compare to the active ingredient in Vicks® Sinex™ Severe Original*

Ultra Fine Mist

12 HOUR

Sinus Relief

OXYMETAZOLINE HCl 0.05%

Nasal decongestant

FOR SINUS RELIEF

- Fast acting day/night relief
- Moisturizing
- Cold & allergy congestion
- Sinus pressure

• Ultra fine pump mist

Actual Bottle Size on Side Panel

IMPORTANT: KEEP THE CARTON FOR FUTURE REFERENCE ON FULL LABELING

Distributed by:

CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895 2019 CVS/pharmacy

CVS.com

1-800-SHOP CVS, V-12431

CVS Quality

Money Back Guarantee

Package contains One Bottle B

PACKAGE LABEL 15 mL

^{*}This product is not manufactured or distributed by Procter and Gamble, the distributer of Vicks[®] SinexTM Severe Original.



Package Label Twin Pack 30 mL



CVS HEALTH ULTRA FINE MIST

oxymetazoline hydrochloride spray

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDO

 Product Type
 HUMAN OTC DRUG
 Item Code (Source)
 NDC:69842-726

 Route of Administration
 NASAL

Active Ingredient/Active Moiety		
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 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CAMPHOR (NATURAL) (UNII: N20HL7Q941)	
EDETATE DISO DIUM (UNII: 7FLD91C86K)	
EUCALYPTOL (UNII: RV6J6604TK)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM PHO SPHATE, DIBASIC, UNSPECIFIED FORM (UNII: GR686LBA74)	
SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW)	

P	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:69842-726- 16	1 in 1 CARTON	03/12/2019				
1		15 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product					
2	NDC:69842-726- 30	2 in 1 CARTON	03/12/2019				
2		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	0 3/12/20 19				

Labeler - CVS PHARMACY, INC. (062312574)

Revised: 9/2019 CVS PHARMACY, INC.