

VICKS SINEX 12 HOUR DECONGESTANT ULTRA FINE MIST - oxymetazoline hydrochloride spray

The Procter & Gamble Manufacturing Company

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.

Vicks® Sinex™

Severe

12 Hour Nasal Decongestant Ultra Fine Mist

Drug Facts

Active ingredient

Oxymetazoline HCl 0.05%

Purpose

Nasal decongestant

Uses

temporarily relieves

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

Warnings

Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to 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 increased 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

Remove protective cap. Before using for the first time, prime the pump by firmly depressing its rim several times. Hold container with thumb at base and nozzle between first and second fingers. Without tilting your head, insert nozzle into nostril. Fully depress rim with a firm, even stroke and inhale deeply.

adults & children 6 yrs. & 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 24 hours.
children 2 to under 6 yrs.	ask a doctor
children under 2 yrs.	do not use

Other information

- store at room temperature

Inactive ingredients

benzalkonium chloride, benzyl alcohol, citric acid anhydrous, edetate disodium, fragrance, polysorbate 80, purified water, sodium citrate, sorbitol

Questions?

1-800-873-8276

Dist. by
Procter & Gamble,
Cincinnati OH 45202.

PRINCIPAL DISPLAY PANEL - 15 mL Bottle Carton

VICKS®

Sinex™

SEVERE

Oxymetazoline HCl-Nasal Decongestant

ORIGINAL

Ultra Fine Mist

- **Fast Sinus Congestion & Pressure Relief**
- **Powerful Vicks Vapors**

12
HOUR

½ FL OZ
(15 ml)



VICKS SINEX 12 HOUR DECONGESTANT ULTRA FINE MIST

oxymetazoline hydrochloride spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37000-433
Route of Administration	NASAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OXYMETAZOLINE HYDROCHLORIDE (UNII: K89MJ0S5VY) (OXYMETAZOLINE - UNII:8VLN5B44ZY)	OXYMETAZOLINE HYDROCHLORIDE	0.0005095 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	white (Clear)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37000-433-01	1 in 1 CARTON	04/27/2015	
1		15 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		
2	NDC:37000-433-02	2 in 1 CARTON	04/27/2015	
2		15 mL in 1 BOTTLE, PUMP; 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	04/27/2015	

Labeler - The Procter & Gamble Manufacturing Company (004238200)