TOPCARE SINUS NASAL- oxymetazoline hydrochloride spray
Topco Associates LLC

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.

Topco Associates LLC. Sinus Nasal Spray Severe 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
- thyroid disease
- diabetes
- high blood pressure
- 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 (1-800-222-1222).

Directions

Shake well before use. Hold white tabs, SQUEEZE grooved area of cap FIRMLY and turn counter clockwise. 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. Secure cap after use.

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 20-25°C (68-77°F)

Inactive ingredients

benzalkonium chloride solution, benzyl alcohol, camphor, dibasic sodium phosphate, edetate disodium, eucalyptol, menthol, microcrystalline cellulose and carboxymethylcellulose sodium, monobasic sodium phosphate, polyethylene glycol, povidone, propylene glycol, purified water

Questions or comments?

1-888-423-0139

Package/Label Principal Display Panel

TopCare® health

COMPARE TO SINEX® SEVERE ACTIVE INGREDIENT

Sinus Nasal Spray

SEVERE

NASAL DECONGESTANT

OXYMETAZOLINE HCl 0.05%

WITH MENTHOL

ULTRA FINE MIST

12 HOUR RELIEF

- Sinus Congestion & Pressure
- Fast & Powerful Relief

1 FL OZ (30 mL)

TOPCARE SINUS NASAL

oxymetazoline hydrochloride spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:36800-711
Route of Administration	NASAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
OXYMETAZOLINE HYDROCHLORIDE (UNII: K89MJ0S5VY) (OXYMETAZOLINE - UNII:8VLN5B44ZY)	OXYMETAZOLINE HYDROCHLORIDE	.05 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM (UNII: GR686LBA74)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
EUCALYPTOL (UNII: RV6J6604TK)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color	WHITE (off white)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:36800-711-10	1 in 1 CARTON	07/17/2018	
1		30 mL in 1 BOTTLE; 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	07/17/2018	

Labeler - Topco Associates LLC (006935977)

Revised: 4/2023 Topco Associates LLC