SUDAFED OM SINUS SEVERE NO DRIP NASAL MIST WITH COOLING MENTHOLoxymetazoline hydrochloride spray Kenvue Brands LLC

SUDAFED® OM Sinus Severe No Drip Nasal Mist with Cooling Menthol Drug Facts

Active ingredient

Oxymetazoline hydrochloride 0.05%

Purpose

Nasal decongestant

Uses

- temporarily relieves nasal congestion due to:
- common cold
- hay fever
- upper respiratory allergies
- temporarily relieves sinus congestion and pressure
- shrinks swollen nasal membranes so you can breathe more freely

Warnings

Warnings

Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- 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

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

- adults and children 6 to under 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 in any 24-hour period.
- children under 6 years of age: ask a doctor

To Use: Shake well before use. Hold white tabs, <u>SQUEEZE</u> grooved area of cap <u>FIRMLY</u> and turn counter clockwise. Before using the first time, prime 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 use. Secure cap after use.

Other information

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

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?

call **1-888-217-2117** (toll-free) or **215-273-8755** (collect)

How to use

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

PRINCIPAL DISPLAY PANEL

NDC 50580-368-01

NEW

SUDAFED ®OM

Oxymetazoline HCl 0.05%,

Nasal Decongestant

NO DRIP

SINUS SEVERE

WITH **COOLING MENTHOL**

- MAXIMUM STRENGTH
- FAST SINUS CONGESTION & PRESSURE RELIEF

COLDS & ALLERGIES

UP TO

12HR

RELIEF

NASAL MIST

1 fl oz (30 mL)



SUDAFED OM SINUS SEVERE NO DRIP NASAL MIST WITH COOLING MENTHOL

oxymetazoline hydrochloride spray

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50580-368
Route of Administration	NASAL		

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

Inactive Ingredients	
Ingredient Name	Strength
EUCALYPTOL (UNII: RV6J6604TK)	
MENTHOL (UNII: L7T10EIP3A)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K6790BS311)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)	
POVIDONE (UNII: FZ 989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:50580-368- 01	1 in 1 CARTON	06/16/2025		
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 Drug	M012	06/16/2025		

Labeler - Kenvue Brands LLC (118772437)

Revised: 5/2025 Kenvue Brands LLC