## SUDAFED OM SINUS SEVERE NO DRIP NASAL MIST- oxymetazoline hydrochloride spray Kenvue Brands LLC

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#### **SUDAFED® OM Sinus Severe No Drip Nasal Mist**

#### **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, dibasic sodiumphosphate, edetate disodium, microcrystalline cellulose and carboxymethylcellulose sodium, monobasic sodium phosphate, polyethylene glycol, povidone, purified water

#### Questions or comments?

**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.

NDC 50580-364-01

NEW

#### **SUDAFED ®OM**

Oxymetazoline HCI 0.05%,

Nasal Decongestant

#### **NO DRIP**

#### **SINUS SEVERE**

- 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

oxymetazoline hydrochloride spray

# Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:50580-364 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	
BENZYL ALCOHOL (UNII: LKG8494WBH)		
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K6790BS311)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
POVIDONE (UNII: FZ 989GH94E)		
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)		
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)		
WATER (UNII: 059QF0KO0R)		
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)		
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)		
EDETATE DISODIUM (UNII: 7FLD91C86K)		

Product Characteristics			
Color	white (White to Off-White)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:50580-364- 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: 4/2025 Kenvue Brands LLC