

**SUNMARK NASAL- oxymetazoline hcl spray**  
**Strategic Sourcing Services 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.*

-----

**McKesson Nasal Spray 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**

**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**

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, SQUEEZE grooved area of cap FIRMLY and turn counter clockwise. Before using the first time, 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 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 sodium phosphate, edetate disodium, microcrystalline cellulose and carboxymethylcellulose sodium, monobasic sodium phosphate, polyethylene glycol, povidone, purified water

**Questions or comments?**

**1-800-719-9260**

**Principal Display Panel**

COMPARE TO AFRIN<sup>®</sup> NO DRIP ACTIVE INGREDIENT

nasal spray

oxymetazoline HCl 0.05% - nasal decongestant

No Drip

Original

Pump mist

Fast, powerful congestion relief

Won't drip from nose or down throat

For colds & allergies

12 HOUR RELIEF

GLUTEN FREE

1 FL OZ (30 mL)

The image shows the packaging for Sunmark Nasal Spray. The main box is blue and white with a yellow sun logo. The text on the box includes 'sunmark', 'COMPARE TO AFRIN® NO DRIP ACTIVE INGREDIENT\*', 'NDC 49348-130-27', 'nasal spray', 'oxymetazoline HCl 0.05% - nasal decongestant', 'No Drip Original', 'Pump mist Fast, powerful congestion relief Won't drip from nose or down throat For colds & allergies', '12 HOUR RELIEF', 'GLUTEN FREE', and '1 FL OZ (30 mL)'. A central illustration shows the white plastic spray bottle with a pump nozzle. The back of the box is also shown, featuring a barcode, the Sunmark logo, and detailed drug facts and directions. The drug facts include active ingredient (Oxymetazoline hydrochloride 0.05%), purpose (nasal decongestant), uses (relieves nasal congestion, sinus congestion, and swollen membranes), warnings (heart disease, high blood pressure, thyroid disease, diabetes, trouble urinating), directions (2 or 3 sprays in each nostril), and other information (store at 20-25°C, retain carton).

## SUNMARK NASAL

oxymetazoline hcl spray

### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:49348-130

Route of Administration NASAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OXYMETAZOLINE HYDROCHLORIDE (UNII: K89MJ0S5VY) (OXYMETAZOLINE - UNII:8VLN5B44ZY)	OXYMETAZOLINE HYDROCHLORIDE	0.05 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM (UNII: GR686LBA74)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
WATER (UNII: 059QF0KO0R)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	

### Product Characteristics

Color	WHITE (to off white, viscous)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49348-130-27	1 in 1 CARTON	09/26/2014	
1		30 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	09/26/2014	

Labeler - Strategic Sourcing Services LLC (116956644)