## SUNMARK NASAL- oxymetazoline hydrochloride 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.

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#### 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: Push firmly down on cap and turn counter clockwise. To spray, squeeze bottle quickly and firmly. Do not tilt head backward while spraying. 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, monobasic sodium phosphate, polysorbate 80, propylene glycol, purified water

#### Questions or comments?

1-800-719-9260

#### **Principal Display Panel**

COMPARE TO AFRIN® ALLERGY SINUS ACTIVE INGREDIENT

nasal spray

oxymetazoline HCl 0.05% - nasal decongestant

Allergy Sinus

Fast, Powerful Congestion Relief from Allergies

Reduces Swelling of Nasal Passages

12 HOUR RELIEF

**GLUTEN FREE** 

1 FL OZ (30 mL)



#### **SUNMARK NASAL**

oxymetazoline hydrochloride spray

# Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:49348-231 Route of Administration NASAL

| Active Ingredient/Active Moiety |                   |          |
|---------------------------------|-------------------|----------|
| Ingredient Name                 | Basis of Strength | Strength |

| OXYMETAZOLINE HYDROCHLORIDE (UNII: K89MJ0S5VY) (OXYMETAZOLINE - | OXYMETAZOLINE | 0.05 g    |
|---|---------------|-----------|
| UNII:8 VLN5B44ZY)   | HYDROCHLORIDE | in 100 mL |

| Inactive Ingredients   |          |
|--|----------|
| Ingredient Name  | Strength |
| BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)                         |          |
| BENZYL ALCOHOL (UNII: LKG8494WBH)                                |          |
| EDETATE DISO DIUM (UNII: 7FLD91C86K)                             |          |
| EUCALYPTOL (UNII: RV6J6604TK)                                    |          |
| MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)                     |          |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H)                                |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                              |          |
| WATER (UNII: 059QF0KO0R)   |          |
| SODIUM PHO SPHATE, DIBASIC, UNSPECIFIED FORM (UNII: GR686LBA74)  |          |
| SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW) |          |

| P | Packaging            |   |                         |                       |  |
|---|----------------------|---|-------------------------|-----------------------|--|
| # | Item Code            | Package Description   | Marketing Start<br>Date | Marketing End<br>Date |  |
| 1 | NDC:49348-231-<br>27 | 1 in 1 CARTON   | 06/24/2003              |                       |  |
| 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                                  | 06/24/2003           |                    |  |  |
|                       |  |                      |                    |  |  |

### Labeler - Strategic Sourcing Services LLC (116956644)

Revised: 5/2020 Strategic Sourcing Services LLC