

TOPCARE 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. 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, 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 AFRIN® NO DRIP ACTIVE INGREDIENT

NO DRIP

Nasal Spray

NASAL DECONGESTANT

OXYMETAZOLINE HCl 0.05%

SEVERE CONGESTION

MENTHOL • PUMP MIST

12 HOUR RELIEF

- Won't Drip from Nose or Down Throat
- Fast, Powerful Congestion Relief
- For Colds & Allergies
- Maximum Strength

1 FL OZ (30 mL)



TOPCARE NASAL

oxymetazoline hydrochloride spray

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:36800-907 |
| 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 |
|---------------------------------------------------------------------------|----------|
| 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: 3WJQ0SDW1A) | |
| POVIDONE, UNSPECIFIED (UNII: FZ989GH94E) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| WATER (UNII: 059QF0KO0R) | |
| BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) | |

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:36800-907-10 | 1 in 1 CARTON | 07/14/2016 | |
| 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 | 07/14/2016 | |

Labeler - Topco Associates LLC (006935977)