TOPCARE NO DRIP EXTRA MOISTURIZING- oxymetazoline hcl 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.

Drug Fact

Active Ingredient
Oxymetazoline Hydrochloride 0.05%

Purpose

Nasal Decongestant

Uses

Temporarily relieves nasal congestion due to:

- common cold
- hay fever
- upper respiroty allergies
- temporarily relieves sinus congestion and pressure
- Shrinks swollen membranes so you can breathe more freely

Warnings

Ask a Doctor before use if you have

- heart diease
- high blood pressure
- diabetes
- thyiod diease
- trouble urinating due to enlarged rostate gland.

When using this product

- **Do not use more than directed**
- do not use for more than three 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 the reach of children

if swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Before using for the first time, remove the protective cap form the tip and prime the 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 nostrile. Fully depress rim with a firm and even stroke, and sniff deeply.
- Wipe nozzle clean after use.
- Adults and children 6 to under 12 years of age (with adult supervision):2 or 3 sprays in each nostril not more than every 10 to 12 hours. Do not exceed 2 doses in any 24-hour period.
- Children under 6 years of age consult a doctor.

Other Information

store between 20° and 25°C (68° to 77°F)
retain carton for future reference on full labeling

Inactive Ingredients

Benzalkonium Chloride Solution, Benzyl Alcohol, Edetate Disodium, Flavor, Glycerin, Microcrystalline Cellulose and Carboxymethylcellulose Sodium, Polyethylene Glycol, Povidone, Purified Water, Sodium Phosphate Dibasic, Sodium Phosphate Monobasic

Principal Panel -Bottle label

TOPCO NDC 36800-561-30

No Drip

Nasal Spray

Oxymetazoline HCL 0.05%Extra Moisturizing

NasaL Decongestant

NET WT 1 FL.OZ (30ml)

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oxymetazoline hcl spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:36800-561
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
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	LEMON	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-561-30	1 in 1 CARTON	04/30/2022	
1		30 mL in 1 BOTTLE, PUMP; 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	04/30/2022	

Labeler - Topco Associates LLC (006935977)

Revised: 4/2022 Topco Associates LLC