NASAL- oxymetazoline hydrochloride spray
Proficient Rx LP

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.

MAJOR®
Soothing - 12 Hour
NASAL
DECONGESTANT
Spray

Drug Facts

Active ingredient

Oxymetazoline hydrochloride 0.05%

Purpose

Nasal decongestant

Uses

- for the temporary relief of nasal congestion due to the common cold, hay fever or other upper respiratory allergies
- shrinks swollen 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 enlarged prostate gland

When using this product

1. **do not exceed recommended dosage**
2. do not use for more than 3 days. Use only as directed.
3. may cause temporary discomfort such as burning, stinging, sneezing, or an increase in nasal discharge
4. the use of this container by more than one person may spread infection
5. frequent or prolonged use may cause nasal congestion to recur or worsen

Stop use and ask 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.

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 within any 24-hour period
- children under 6 years of age: consult a doctor

To spray, squeeze bottle quickly and firmly. Do not tilt head backward while spraying. Wipe nozzle clean after use

Other information

- store between 20° to 25° C (68° to 77° F)

Inactive ingredients

benzalkonium chloride, benzyl alcohol, dibasic sodium phosphate, edetate disodium, hydrochloric acid, monobasic sodium phosphate, polyethylene glycol 1450, povidone, propylene glycol, purified water

Questions?

To Report Adverse Drug Event Call: (800) 616-2471

PRINCIPAL DISPLAY PANEL - 15 mL Carton

NDC 63187-701-15

Relabeled by:

Proficient Rx LP, Thousand Oaks, CA 91320

Soothing - 12 Hour
NASAL
DECONGESTANT
Spray

REGULAR

oxymetazoline
hydrochloride
0.05%

RELIEVES
CONGESTION
FAST

Compare to
active ingredient
of Afrin®

1/2 FL.OZ.
(15 mL)

NASAL

oxymetazoline hydrochloride spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63187-701(NDC:0904-5711)
Route of Administration	NASAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Oxymetazoline Hydrochloride (UNII: K89MJ0S5VY) (Oxymetazoline - UNII:8VLN5B44ZY)	Oxymetazoline Hydrochloride	5 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	
Benzalkonium Chloride (UNII: F5UM2KM3W7)	
Edetate Disodium (UNII: 7FLD91C86K)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Benzyl Alcohol (UNII: LKG8494WBH)	
SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM (UNII: GR686LBA74)	
SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
Hydrochloric Acid (UNII: QTT17582CB)	
Polyethylene Glycol 1450 (UNII: OJ4Z5Z32L4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63187-701-15	15 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/02/2016	
2	NDC:63187-701-30	30 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/02/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/17/2009	

Labeler - Proficient Rx LP (079196022)

Establishment

Name	Address	ID/FEI	Business Operations
Proficient Rx LP		079196022	RELABEL(63187-701)

Revised: 11/2019 Proficient Rx LP