OXYMETAZOLINE HYDROCHLORIDE 12-HOUR- oxymetazoline hydrochloride spray
Taro Pharmaceuticals U.S.A., Inc.

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.

Oxymetazoline Hydrochloride
Nasal Decongestant 12-Hour Spray

Drug Facts

Active ingredient

Oxymetazoline hydrochloride 0.05%

Purpose

Nasal decongestant

Uses

- temporary relief of nasal congestion
  - due to the common cold
  - due to hay fever or other upper respiratory allergies
  - associated with sinusitis
- reduces swelling of nasal passages
- temporarily restores freer breathing through the nose

Warnings

Do not exceed recommended dosage

This product may cause temporary discomfort such as burning, stinging, sneezing, or an increase in nasal discharge. The use of this container by more than one person may spread infection.

Do not use

- for more than 3 days

Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- difficulty in urination due to enlargement of the prostate gland

When using this product

- frequent or prolonged use may cause nasal congestion to recur or worsen

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.

Directions

- Adults and children 6 to under 12 years of age (with supervision): 2 to 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 spray: squeeze the bottle quickly and firmly. Do not tilt head backward while spraying. Wipe nozzle clean after use.

Inactive ingredients

benzalkonium chloride, dibasic sodium phosphate (anhydrous), edetate disodium (dihydrate), monobasic sodium phosphate (monohydrate), polyethylene glycol 1450, povidone, propylene glycol, purified water.

Questions?

Call 1-866-923-4914

Distributed by:
Taro Pharmaceuticals U.S.A., Inc.
Hawthorne, NY 10532

PRINCIPAL DISPLAY PANEL - 30 mL Bottle Carton

Compare to the
active ingredient
in Afrin ®*

Nasal
Decongestant
12- Hour Spray

Oxymetazoline
Hydrochloride 0.05%

Maximum Strength

- *Fast Acting*
- *Up To 12 Hours Relief*

Contains the Active Ingredient
Recommended Most by
Physicians and Pharmacists

12

1 fl oz (30 mL)

OXYMETAZOLINE HYDROCHLORIDE 12-HOUR

oxymetazoline hydrochloride spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51672-2030
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)	
sodium phosphate, dibasic, anhydrous (UNII: 22ADO53M6F)	
edetate disodium (UNII: 7FLD91C86K)	
sodium phosphate, monobasic, monohydrate (UNII: 593YOG76RN)	
polyethylene glycol 1450 (UNII: OJ4Z5Z32L4)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
propylene glycol (UNII: 6DC9Q167V3)	
water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51672-2030-5	1 in 1 CARTON	02/25/2006	
1		15 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		
2	NDC:51672-2030-3	1 in 1 CARTON	02/25/2006	
2		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	02/25/2006	

Labeler - Taro Pharmaceuticals U.S.A., Inc. (145186370)

Establishment

Name	Address	ID/FEI	Business Operations
Applied Laboratories, Inc.		117337220	MANUFACTURE(51672-2030)

Revised: 1/2019 Taro Pharmaceuticals U.S.A., Inc.