

NASAL DECONGESTANT EXTRA MOISTURIZING- oxymetazoline hcl spray Kareway Product, 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.

Pure-Aid Nasal Spray Extra-Moisturizing

Active ingredient

Oxymetazoline HCl 0.05%

Purpose

Nasal decongestant

Uses

- temporarily relieves nasal congestion due to:
 - common cold
 - hay fever
 - upper respiratory allergies
 - sinusitis
- reduces swelling of nasal passages; shrinks swollen membranes
- temporarily restores freer breathing through the nose

Warnings

Do not use this product 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

When using this product

- **do not exceed recommended dosage**
- use only as directed. frequent or prolonged use may cause nasal congestion to recur or worsen
- temporary discomfort such as burning, stinging, 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.

Directions

- Shake well before use.
- To spray, remove the clear plastic cap.
- Hold bottle with thumb at base and nozzle between first and second fingers. If this is the first time you are using the pump, spray several times into the air until you get a fine mist. If you have not used the pump for 14 days, spray several times into the air before using again.
- Insert nozzle into nostril. Spray upward while breathing in through the nose. Repeat in other nostril.
- Wipe nozzle clean after use. Put clear plastic cap back on the bottle
- Do not exceed 2 doses in any 24 hour period.

adults and children 6 to under 12 years of age (with adult supervision)	2 or 3 spray in each nostril not more often than every 10 to 12 hours
children under 6 years of age	ask a doctor

Other information

- store at room temperature(59°~86°F)
- retain carton for future reference on full labeling

Inactive ingredients

benzalkonium chloride, concentrated glycerin, edetate disodium, purified water

Carton image

Nasal Spray Extra Moisturizing



NASAL DECONGESTANT EXTRA MOISTURIZING

oxymetazoline hcl spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67510-0069
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)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67510-0069-5	1 in 1 BOX	07/03/2013	
1		15 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		
2	NDC:67510-0069-1	1 in 1 BOX	07/03/2013	
2		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	08/12/2011	

Labeler - Kareway Product, Inc. (121840057)

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Kareway Product, Inc.