

REXALL SINUS NASAL PUMP MIST- oxymetazoline hydrochloride 0.05% liquid

Dollar General

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 Facts

Active ingredients

Oxymetazoline Hydrochloride 0.05%

Purpose

Nasal Decongestant

Uses

temporarily relieve nasal congestion due to:

- common cold
- hay fever
- upper respiratory allergies
- shrinks swollen membranes
- temporarily restores freer breathing through the nose

Do not use this product if person has heart disease, high blood pressure, thyroid disease, diabetes, or if adult has difficulty in urination due to enlargement of the prostate gland unless directed by a doctor.

When using this product

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

Stop use and ask doctor if

Symptoms persist

If pregnant or breast-feeding, ask a health professional before use

Keep out of reach of the children

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: consult a doctor

shake well before each use. Before using for the first time remove the protective cap from the tip and prime mitered pump by depressing pump firmly several times. To remove the cap, squeeze cap at the base on opposite sides on the two smooth impressions with fingers. While squeezing, twist cap counterclockwise to remove. Remove clip and press down to use. Refer to directions on top of each cap. To reapply cap, turn cap on pump clockwise until it locks. 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.

Inactive ingredients

Benzalkonium Chloride

Camphor
 Disodium EDTA
 Disodium Phosphate
 Eucalyptol
 Menthol
 Polysorbate 20
 Propylene Glycol
 Sodium Phosphate
 Water



REXALL SINUS NASAL PUMP MIST

oxymetazoline hydrochloride 0.05% liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:559 10-778
Route of Administration	TOPICAL		

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)				
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)				
EDETATE DISODIUM (UNII: 7FLD91C86K)				
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)				
EUCALYPTOL (UNII: RV6J6604TK)				
Menthol (UNII: L7T10EIP3A)				
Polysorbate 20 (UNII: 7T1F30V5YH)				
Propylene Glycol (UNII: 6DC9Q167V3)				
Sodium Phosphate (UNII: SE337SVY37)				
Water (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-778-01	30 mL in 1 PACKAGE; Type 0: Not a Combination Product	12/21/2015	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	12/21/2015		

Labeler - Dollar General (068331990)

Registrant - Product Quest Mfg (927768135)

Establishment

Name	Address	ID/FEI	Business Operations
Product Quest Mfg		927768135	manufacture(55910-778) , label(55910-778)

Revised: 10/2017

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