NASAL MIST WALGREENS- oxymetazoline hydrochloride 0.05% liquid Walgreens

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 ingredient

Purpose

Oxymetazoline Hydrochloride 0.05%

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

Do not use this product if you have heart disease • high blood pressure • thyroid disease • diabetes • or difficulty in urination due to enlargement of the prostate gland

When using this product

•do not exceed recommended dosage • do not use for more than 3 days. Use only as directed. • 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 • frequent or prolonged use may cause nasal congestion to recur or worsen

Keep out of reach of children. If product is swallowed, get medical help or contact a PoisonControl Center right away

Directions

Before using the first time, remove the protective cap from the tip and prime 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 nostril. Fully depress rim with a firm, even stroke and sniff deeply. Wipe nozzle clean after use. • adults and children 6 to under 1 2 years of age (with adult supervision): 2 or 3 sprays in each nostril not more often than every 1 0 to 1 2 hours. Do not exceed 2 doses within any 24-hour period • children under 6 years of age: consult a doctor

Inactive ingredients

Benzalkonium Chloride Chlorhexidine Gluconate Citric Acid
Disodium EDTA
Fragrance
Purified Water
Sodium Citrate
Sodium Hydroxide
Tyloxapol



DO NOT USE IF PRINTED SEAL OVER CAP IS TORN OR MISSING

Drug Facts

Active ingredient

Purpose

Oxymetazoline hydrochloride 0.05%.....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

Do not use if you have

- heart disease
 high blood pressure
 thyroid disease
- diabetes trouble urinating due to enlarged prostate gland unless directed by a doctor

When using this product

- · do not exceed recommended dosage
- · do not use for more than 3 days. Use only as directed.
- 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
- 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

Before using the first time, remove the protective cap from the tip and prime 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 nostril. Fully depress rim with a firm, even stroke and sniff deeply. Wipe nozzle clean after use.

- adults and children 6 to under 12 years of age (with adult supervision): 1 or 2 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

Walgreens Pharmacist Recommended Walgreens Pharmacist Survey This product is not manufactured or distributed by Procter & Gamble, the distributor of Vicks Sinex Sin

Drug Facts (continued)

Other information

Store between 15°-30° C (59'- 86° F)

Inactive ingredients

Benzalkonium Chloride, Chlorhexidine Gluconate, Citric Acid, Disodium EDTA, Fragrance, Purified Water, Sodium Citrate, Sodium Hydroxide, Tyloxapol.

IMPORTANT:

KEEP OUTER CARTON FOR FUTURE REFERENCE ON FULL LABELING

Cap Removal Instructions:

To remove cap, squeeze cap at 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 cap.

To reapply cap, turn cap on pump clockwise until it locks.

Questions or comments? 1-866-483-2846

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NASAL MIST WALGREENS

oxymetazoline hydrochloride 0.05% liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:0363-7000

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)	
Water (UNII: 059QF0KO0R)	
Chlorhexidine Gluconate (UNII: MOR84MUD8E)	
CITRIC ACID MONO HYDRATE (UNII: 2968 PHW8 QP)	
EDETATE DISO DIUM (UNII: 7FLD91C86K)	
Sodium Citrate (UNII: 1Q73Q2JULR)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Tyloxapol (UNII: Y27PUL9H56)	

F	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-7000-01	1 in 1 CARTON	07/01/2016	
1		15 mL in 1 BOTTLE; 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	07/01/2016		

Labeler - Walgreens (008965063)

Registrant - Product Quest Mfg, LLC (927768135)

Establishment			
Name	Address	ID/FEI	Business Operations
Product Quest Mfg, LLC		927768135	manufacture(0363-7000), label(0363-7000)

Revised: 6/2018 Walgreens