SEVERE CONGESTION NASAL NO DRIP 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

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

•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

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 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, Benzyl Alcohol, Camphor, Edetate Disodium, Eucalyptol, Menthol,

Microcrystalline Cellulose, Polyethylene Glycol, Povidone, Propylene Glycol, Purified Water, Sodium Carboxymethyl Cellulose, Sodium Phosphate Dibasic, Sodium Phosphate Monobasic.



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

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- 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): 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
- *Walgreens Pharmacist Survey Study, November 2014.
- ^{‡‡}This product is not manufactured or distributed by Bayer HealthCare LLC, the distributor of Afrin® No Drip Severe Congestion Pump Mist.

Drug Facts (continued)

Other information

Store between 15'-30° C (59'-86° F)

Inactive ingredients

Benzalkonium Chloride, Benzyl Alcohol, Camphor, Edetate Disodium, Eucalyptol, Menthol, Microcrystalline Cellulose, Polyethylene Glycol, Povidone, Propylene Glycol, Purified Water, Sodium Carboxymethyl Cellulose, Sodium Phosphate Dibasic, Sodium Phosphate Monobasic.

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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SEVERE CONGESTION NASAL NO DRIP WALGREENS

oxymetazoline hydrochloride 0.05% liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:0363-7001

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
1 2 3 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Oxymetazoline Hydrochloride	0.05 g in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
Benzalkonium Chloride (UNII: F5UM2KM3W7)	
Benzyl Alcohol (UNII: LKG8494WBH)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
Edetate Disodium (UNII: 7FLD91C86K)	
Eucalyptol (UNII: RV6J6604TK)	
Menthol (UNII: L7T10EIP3A)	
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
Povidone (UNII: FZ989GH94E)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Water (UNII: 059QF0KO0R)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679 OBS 311)	
SO DIUM PHO SPHATE, DIBASIC, ANHYDRO US (UNII: 22ADO53M6F)	
SO DIUM PHO SPHATE, MO NO BASIC, ANHYDRO US (UNII: KH710 4HPUU)	

	Packaging				
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	NDC:0363-7001-01	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(0363-7001), label(0363-7001)	

Revised: 2/2018 Walgreens