NASAL- oxymetazoline hydrochloride spray Rite Aid Corporation

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.

Rite Aid Corporation Nasal Spray Drug Facts

Active ingredient

Oxymetazoline hydrochloride 0.05%

Purpose

Nasal decongestant

Uses

- temporarily relieves nasal congestion due to:
- common cold
- hay fever
- upper respiratory allergies
- temporarily relieves sinus congestion and pressure
- shrinks swollen nasal 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 an enlarged prostate gland

When using this product

- do not use more than directed
- do not use for more than 3 days. Use only as directed. Frequent or prolonged use may cause nasal congestion to recur or worsen.
- temporary discomfort such as burning, stinging, sneezing 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 (1-800-222-1222).

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: ask a doctor

To Use: Shake well before use. Hold white tabs, <u>SQUEEZE</u> grooved area of cap <u>FIRMLY</u> and turn counter clockwise. Before using the first time, prime metered 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. Secure cap after use.

Other information

- store at 20-25°C (68-77°F)
- retain carton for future reference on full labeling

Inactive ingredients

benzalkonium chloride solution, benzyl alcohol, camphor, dibasic sodium phosphate, edetate disodium, eucalyptol, menthol, microcrystalline cellulose and carboxymethylcellulose sodium, monobasic sodium phosphate, polyethylene glycol, povidone, propylene glycol, purified water

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

Compare to the active ingredient of Afrin® No Drip Severe Congestion

SEVERE CONGESTION nasal relief

nasal spray

oxymetazoline HCl 0.05%

nasal decongestant

NO DRIP

12 HOUR

pump mist

plus menthol

fast, powerful congestion relief for colds & allergies



NASAL

oxymetazoline hydrochloride spray

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:11822-6378 Route of Administration NASAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OXYMETAZOLINE HYDROCHLORIDE (UNII: K89MJ0S5VY) (OXYMETAZOLINE - UNII:8 VLN5B44ZY)	OXYMETAZOLINE HYDROCHLORIDE	.05 g in 100 mL	

Inactive Ingredients		
Ingredient Name	Strength	
BENZYL ALCOHOL (UNII: LKG8494WBH)		
SO DIUM PHO SPHATE, DIBASIC (UNII: GR686LBA74)		
EDETATE DISO DIUM (UNII: 7FLD91C86K)		
EUCALYPTOL (UNII: RV6J6604TK)		
MENTHOL (UNII: L7T10EIP3A)		
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)		
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679 OBS311)		
SODIUM PHO SPHATE, MO NO BASIC (UNII: 3980 JIH2SW)		
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)		
PO VIDO NE (UNII: FZ989GH94E)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7)		

Product Characteristics			
Color	WHITE (off white)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

]	Packaging			
#	t Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-6378-	1 in 1 CARTON	12/05/2018	
1		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	12/05/2018	

Labeler - Rite Aid Corporation (014578892)

Revised: 12/2018 Rite Aid Corporation