## 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.

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#### **Rite Aid Corporation Nasal Spray Drug Facts**

#### **Active ingredient**

Oxymetazoline HCl 0.05%

#### Purpose

Nasal decongestant

#### Uses

temporarily relieves

- nasal congestion due to a cold, hay fever, or other upper respiratory allergies
- sinus congestion and pressure

#### Warnings

#### Ask a doctor before use if you have

- heart disease
- thyroid disease
- diabetes
- high blood pressure
- trouble urinating due to an enlarged prostate gland

#### When using this product

- do not exceed recommended dosage
- do not use this product 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**

Shake well before use. Hold white tabs, <u>SQUEEZE</u> grooved area of cap <u>FIRMLY</u> and turn counter clockwise. Before using for the first time, prime the pump by firmly depressing its rim several times. Hold container with thumb at base and nozzle between first and second fingers. Without tilting your head, insert nozzle into nostril. Fully depress rim with a firm, even stroke and inhale deeply. Secure cap after use.

adults & children	2 or 3 sprays in each nostril, not
6 yrs. & older	more often than every 10 to 12 hours.
(with adult supervision)	Do not exceed 2 doses in 24 hours.
children 2 to under 6 yrs.	ask a doctor
children under 2 yrs.	do not use

#### Other information

• store at 20-25°C (68-77°F)

#### **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 Sinex<sup>®</sup> Severe

severe

nasal relief

nasal spray

oxymetazoline HCl 0.05%

nasal decongestant

12 HOUR

sinus congestion & pressure

fast & powerful relief

ultra fine mist with menthol

1 FL OZ (30 mL)



#### **NASAL**

oxymetazoline hydrochloride spray

# Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:11822-6623 Route of Administration NASAL

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

Inactive Ingredients		
Ingredient Name	Strength	
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7)		
BENZYL ALCOHOL (UNII: LKG8494WBH)		
SO DIUM PHO SPHATE, DIBASIC (UNII: GR686LBA74)		
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)		
EUCALYPTOL (UNII: RV6J6604TK)		
MENTHOL (UNII: L7T10EIP3A)		
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)		
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679 OBS 311)		
SODIUM PHO SPHATE, MO NO BASIC (UNII: 3980 JIH2 SW)		
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)		
PO VIDO NE (UNII: FZ989 GH9 4E)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		

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:11822-6623-	1 in 1 CARTON	12/05/2018	
1		30 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		

<b>Marketing Info</b>	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