

MUCINEX CHILDRENS STUFFY NOSE- oxymetazoline hydrochloride solution RB Health (US) LLC

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.

MUCINEX® Children's Stuffy Nose Spray

Drug Facts

Active ingredient

Oxymetazoline hydrochloride 0.05%

Purpose

Nasal decongestant

Uses

- temporarily relieves nasal congestion due to:
 - a cold
 - hay fever or other upper respiratory allergies
- promotes nasal and sinus drainage; temporarily relieves sinus congestion and pressure
- helps clear nasal passages; shrinks swollen membranes

Warnings

Ask a doctor before use if you or the child has

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- difficulty in urination due to enlargement of the 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
- 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 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

- 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 use. To open, hold by the white grips then squeeze and turn cap. Before using for the first time, remove the protective cap from the tip and prime metered pump by depressing firmly several times. To spray, hold bottle with thumb at the base and nozzle between first and second fingers. Without tilting head, insert nozzle into nostril. Fully depress pump all the way down with a firm even stroke and sniff deeply. Wipe nozzle clean after use. To close, turn cap until it "clicks".

DO NOT DISCARD CAP

Other information

- store between 20-25°C (68-77°F)

Inactive ingredients

benzalkonium chloride, camphor, edetate disodium, eucalyptol, glycine, menthol, polyethylene glycol, polysorbate 80, propylene glycol, purified water, sodium chloride, sodium hydroxide

Questions?

1-866-MUCINEX (1-866-682-4639)

You may also report side effects to this number.

Dist. by: RB Health (US)
Parsippany, NJ 07054-0224

Made in India

PRINCIPAL DISPLAY PANEL - 22 mL Bottle Carton

NDC 63824-961-22

Mucinex®

Children's

**STUFFY NOSE
SPRAY**

Oxymetazoline HCl 0.05%

Nasal Decongestant

**12
HOUR**

- ✓ **Fast Relief
of Stuffy Nose**

**Ages 6+
yrs**

**3/4 FL OZ (22 mL)
NASAL SPRAY**



MUCINEX CHILDRENS STUFFY NOSE

oxymetazoline hydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63824-961	
Route of Administration	NASAL			
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)				
edetate disodium (UNII: 7FLD91C86K)				
eucalyptol (UNII: RV6J6604TK)				
glycine (UNII: TE7660XO1C)				
menthol, unspecified form (UNII: L7T10EIP3A)				
polyethylene glycol, unspecified (UNII: 3WJQ0SDW1A)				
polysorbate 80 (UNII: 6OZP39ZG8H)				
propylene glycol (UNII: 6DC9Q167V3)				
water (UNII: 059QF0K00R)				
sodium chloride (UNII: 451W47IQ8X)				
sodium hydroxide (UNII: 55X04QC32I)				
camphor (synthetic) (UNII: 5TJD82A1ET)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-961-22	1 in 1 CARTON	03/30/2018	
1		22 mL in 1 BOTTLE, PUMP; 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	03/30/2018		

Labeler - RB Health (US) LLC (081049410)