# NASAL RELIEF 12-HOUR- oxymetazoline hydrochloride spray Rugby Laboratories

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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# Oxymetazoline Hydrochloride Nasal Decongestant 12-Hour Spray

#### Drug Facts

#### **Active ingredient**

Oxymetazoline hydrochloride 0.05%

## **Purpose**

Nasal decongestant

#### Uses

- temporary relief of nasal congestion
  - due to the common cold
  - due to hay fever or other upper respiratory allergies
  - associated with sinusitis
- temporarily restores freer breathing through the nose

# Warnings

#### Do not exceed recommended dosage

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.

#### Do not use

• for more than 3 days

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

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

#### When using this product

- frequent or prolonged use may cause nasal congestion to recur or worsen
- do not use more than directed
- there may be temporary discomfort such as burning, stinging, sneezing or an increase in nasal discharge
- use only as directed as frequent or prolonged use may cause nasal congestion to recur or worsen
- infection may spread if container is used by more than one person

#### Stop use and ask a doctor if

• symptoms persist

### If pregnant or breast feeding

**If pregnant or breast-feeding,** ask a health professional before use.

# Keep out of reach of children

**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 to 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: do not use
- To spray: squeeze the bottle quickly and firmly. Do not tilt head backward while spraying. Wipe nozzle clean after use.

# **Inactive ingredients**

benzalkonium chloride, dibasic sodium phosphate (anhydrous), edetate disodium (dihydrate), monobasic sodium phosphate (monohydrate), purified water, sodium chloride, sorbitol

#### Questions?

Call 1-866-645-2158

Distributed by:

Rugby Laboratories Livonia, MI 48150 USA

#### PRINCIPAL DISPLAY PANEL - 15 mL Bottle Carton

Compare to the active ingredient in Afrin ®\*

Nasal Decongestant 12- Hour Spray

Oxymetazoline Hydrochloride 0.05%

#### **Maximum Strength**

- Fast Acting
- Up To 12 Hours Relief



#### **NASAL RELIEF 12-HOUR**

oxymetazoline hydrochloride spray

<b>Product Information</b>			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:0536-5005
Route of Administration	NASAL	DEA Sche dule	

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
O XYMETAZOLINE HYDRO CHLO RIDE (O XYMETAZOLINE)	OXYMETAZOLINE HYDROCHLORIDE	0.05 g in 100 mL		

Inactive Ingredients			
Ingredient Name	Strength		
BENZALKO NIUM CHLO RIDE			
SO DIUM PHO SPHATE, DIBASIC, ANHYDRO US			
EDETATE DISO DIUM			
SO DIUM PHO SPHATE, MO NO BASIC, MO NO HYDRATE			
WATER			
SO DIUM CHLO RIDE			
SORBITOL			

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:0536-5005-72	1 in 1 CARTON			
1	15 mL in 1 BOTTLE, SPRAY			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC MONOGRAPH FINAL	part341	10/29/2012			

# Labeler - Rugby Laboratories (191427277)

Revised: 1/2013 Rugby Laboratories