

**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<sup>®\*</sup>

**Nasal**  
**Decongestant**  
**12- Hour Spray**

**Oxymetazoline**  
**Hydrochloride 0.05%**

**Maximum Strength**

- *Fast Acting*
- *Up To 12 Hours Relief*

**Drug Facts (continued)**  
**Directions**  
 adults and children 6 years and over (with adult supervision):  
 ■ 2-3 sprays in each nostril every 10-12 hours  
 ■ do not exceed 2 doses in any 24-hour period  
 children under 6 years: do not use  
 To spray, squeeze the bottle quickly and firmly. Do not tilt head back while spraying. Wipe nozzle clean after use.

**Inactive ingredients**  
 benzalkonium chloride, disodium edetate, disodium phosphate, monosodium phosphate, purified water, sodium chloride, sorbitol

**Questions or comments?**  
 Call 1-800-646-2158, 9 am - 5 pm ET, Monday - Friday

SAVE BOX FOR COMPLETE PRODUCT INFORMATION  
**TAMPER EVIDENT: DO NOT USE IF IMPRINTED SEAL ON CAP IS BROKEN OR MISSING**  
 Store between 2° - 30°C (36° - 86°F).  
 Lot No. & Exp. Date: See label, bottom of container or box.

\*Rugby Laboratories, Inc. is not affiliated with the owner of the registered trademark Afrin®.

Rugby Nasal Relief Spray is distributed by Rugby Laboratories, Inc.  
 Duluth, Georgia 30097  
 www.rugbylaboratories.com  
 ROS10

**Drug Facts**  
**Active ingredient Purpose**  
 Oxymetazoline HCl, 0.05%...Nasal Decongestant

**Uses temporarily**  
 ■ relieves nasal congestion due to the common cold, hay fever, or other upper respiratory allergies  
 ■ restores freer breathing through the nose

**Warnings**  
 Do not use for more than 3 days  
**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  
 ■ 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 last**  
 If pregnant or breast-feeding, ask a health professional before use.  
 Keep out of reach of children. In case of overdose or if swallowed, get medical help or contact a Poison Control Center right away.

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 17  
 100%

## NASAL RELIEF 12-HOUR

oxymetazoline hydrochloride spray

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0536-5005
<b>Route of Administration</b>	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)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN)	
WATER (UNII: 059QF0K00R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SORBITOL (UNII: 506T60A25R)	

**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