



RUGBY LABORATORIES  
A Division of Watson Pharma, Inc.

February 25, 2003

Dockets Management Branch  
Food & Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**Subject: DOCKET NO. 98N-1109**

Dear Sir/Madam;

With reference to your request for information on Mercury Compounds in Drugs and Food, please note that RUGBY LABORATORIES does not market any products containing mercury compounds.

There is only one Rugby product on your current list, Nasal Relief Spray Long Acting. In September 2000, Rugby changed its supplier of this product from Hi-Tech Pharmacal to Applied Laboratories. The formulation from this new supplier does not contain any mercury compounds.

I am attaching copies of the current labeling as well as some from Altaire Pharmaceuticals who is to be our new supplier.

If you have any questions, you may contact me at 1-800-645-2158, ext. 104.

Sincerely,

A handwritten signature in cursive script that reads "Sue Crane".

Sue Crane  
Manager, QA & Regulatory Affairs  
OTC Division

98N-1109

LETI

mfr =  
APPLIED LABS



1 fl oz (30 mL)

# NASAL RELIEF SPRAY

Prod No. 603-5000



Drug Facts	
<b>Active ingredient</b> Oxymetazoline HCl 0.05% .....	<b>Purpose</b> Nasal Decongestant
<b>Uses</b> temporarily • relieves nasal congestion due to the common cold, hay fever or upper respiratory allergies • restores freer breathing through the nose	
<b>Warnings</b> <b>Do not use</b> for more than 3 days <b>Ask doctor before use if you have</b> • diabetes • heart disease • thyroid disease • high blood pressure • trouble urinating due to an enlarged prostate gland	
<b>When using this product</b> • <b>do not use more than directed</b> • 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	
<b>Stop use and ask a doctor if symptoms last</b> <b>If pregnant or breast-feeding</b> , ask a health professional before use. <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away	

### 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 take more than 2 doses in 24 hours  
**children under 6 years:**  
ask a doctor  
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), polyethylene glycol 1450, povidone, propylene glycol, purified water

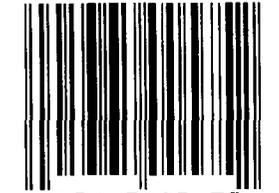
**TAMPER EVIDENT:  
DO NOT USE IF IMPRINTED  
SAFETY BAND AROUND BOTTLE  
IS BROKEN OR MISSING**

**SAVE BOX FOR COMPLETE  
PRODUCT INFORMATION**

Store between  
15° - 30°C (59° - 86°F)

FOR LOT NO AND EXP DATE,  
SEE BOTTOM OF PRODUCT CARTON

PK-3755-0 0401-0 C



0 0536-5005-75 2

NDC 0536-5005-75

COMPARE TO ACTIVE INGREDIENT IN AFRIN®

SPRAY

Oxymetazoline Hydrochloride 0.05%

SPRAY

Oxymetazoline Hydrochloride 0.05%

SAFETY BAND

Durham, Georgia 28837

Made in U.S.A.

R0301

1 fl oz (30 mL)

SATISFACTION GUARANTEED  
**Rugby**  
OR YOUR MONEY BACK

mfr =  
ALTAIRE PHARMACEUTICAL

1 fl oz (30 mL)

**NASAL RELIEF SPRAY**

Prod No 503-5000



**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: ask a doctor

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

SAVE BOX FOR COMPLETE PRODUCT INFORMATION

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED SEAL ON CAP IS BROKEN OR MISSING**

Store between 2° and 30°C (36° and 86°F). Lot No. & Exp. Date: See label, bottom of container or box.

NDC 0536-5005-75



**NASAL RELIEF SPRAY**

**NRS**

Oxymetazoline Hydrochloride 0.05%



1 fl oz (30 mL)

COMPARE TO ACTIVE INGREDIENT IN AFRIN®



**NASAL RELIEF SPRAY**

**NRS**

Oxymetazoline Hydrochloride 0.05%

R1102

**Drug Facts**

**Active ingredient** Oxymetazoline HCl, 0.05% ..... **Purpose** 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 exceed recommended dosage**
- 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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