

RUGBY NASAL DECONGESTANT NASAL DECONGESTANT- pseudoephedrine hydrochloride liquid

Dispensing Solutions, Inc.

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.

**Rugby®
NASAL
DECONGESTANT
LIQUID**

Drug Facts

Active ingredient (in each teaspoonful [TSP])

Pseudoephedrine HCl 30 mg

Purpose

Nasal decongestant

Uses

temporarily relieves nasal congestion due to

- common cold
- hay fever
- upper respiratory allergies

Warnings

Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's Disease), or for two weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask your doctor or pharmacist before taking this product.

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 use more than directed**

Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- symptoms do not improve within 7 days or occur with fever

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

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control

Center right away.

Directions

- take every 4-6 hours
- do not take more than 4 doses in 24 hours
- use only with enclosed dose cup. Do not use with any other device.

adults & children 12 years and over	2 TSP
children 6 to under 12 years	1 TSP
children under 6 years	do not use

Other information

- store at room temperature 15°-30°C (59°-86°F)
- protect from light

Inactive ingredients

artificial raspberry flavor, citric acid, FD&C red #40, glycerin, methylparaben, purified water, saccharin sodium, sodium benzoate, sorbitol solution

Questions or comments?

Call **1-800-645-2158**, 9 am - 5 pm ET, Monday - Friday

Mfd. for:

Rugby Laboratories, Inc.
Duluth, Georgia 30097

PRINCIPAL DISPLAY PANEL

<p>BULK SOURCE DATA MFD. FOR: RUGBY LABORATORIES, INC. DULUTH, GA 30097</p> <p>PRODUCT ID: BLUE / WHITE / RED / YELLOW / LIGHT BLUE / BLACK BOX PRINTED NDC 0536-1850-97</p> <p>BULK SOURCE NDC: 00536-1850-97 MFR. LOT: XXXXXX PEDIGREE #: 17687351 DISPENSE IN THIS TIGHT/LIGHT RESISTANT CONTAINER</p> 	 <p>PSEUDOEPHEDRINE HCl 30 mg</p> <p>4 fl oz LIQUID</p> <p>NDC 68258-8000-04 PRODUCT # 8P0304</p> <p>Rev. Date: 01/10</p> <p>EACH 5 mL TEASPOONFUL CONTAINS: PSEUDOEPHEDRINE HYDROCHLORIDE 30 mg (PURPOSE: NASAL DECONGESTANT)</p> <p>LOT# SAMPLE EXP: 00-00 Rx # 20981801</p>	<p>WARNING: KEEP OUT OF CHILDREN'S REACH STORE AT 59°- 86° F</p> <p>8P0304 NDC 68258-8000-04 PSEUDOEPHEDRINE HCl 30 mg 4 fl oz LIQUID LOT # SAMPLE EXP: 00-00 MN 00536-1850-97 RX# 20981801</p> <p>8P0304 NDC 68258-8000-04 PSEUDOEPHEDRINE HCl 30 mg 4 fl oz LIQUID LOT # SAMPLE EXP: 00-00 MN 00536-1850-97 RX# 20981801</p> <p>8P0304 NDC 68258-8000-04 PSEUDOEPHEDRINE HCl 30 mg 4 fl oz LIQUID LOT # SAMPLE EXP: 00-00 MN 00536-1850-97 RX# 20981801</p>  <p>Packaged Exclusively By: DISPENSING SOLUTIONS <small>INC.</small> Santa Ana, CA 92704</p>
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NDC 68258-8000-04

NASAL DECONGESTANT
LIQUID

Pseudoephedrine HCl 30 mg

TEMPORARILY RELIEVES NASAL CONGESTION DUE TO COLDS AND ALLERGIES
WITHOUT DROWSINESS

•SATISFACTION GUARANTEED•

4 fl oz
(118 mL)

RUGBY NASAL DECONGESTANT NASAL DECONGESTANT

pseudoephedrine hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68258-8000(NDC:0536-1850)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Pseudoephedrine Hydrochloride (UNII: 6V9V2RYJ8N) (Pseudoephedrine - UNII:7CUC9DDI9F)	Pseudoephedrine Hydrochloride	30 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
Sorbitol (UNII: 506T60A25R)	
Citric Acid Monohydrate (UNII: 2968PHW8QP)	
Methylparaben (UNII: A2I8C7HI9T)	
FD&C Red no. 40 (UNII: WZB9127XOA)	
Glycerin (UNII: PDC6A3C0OX)	
Raspberry (UNII: 4N14V5R27W)	
Water (UNII: 059QF0KO0R)	
Sodium Benzoate (UNII: OJ245FE5EU)	
Saccharin Sodium (UNII: SB8ZUX40TY)	

Product Characteristics

Color	red	Score	
Shape		Size	
Flavor	RASPBERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68258-8000-4	118 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/26/1999	

Labeler - Dispensing Solutions, Inc. (066070785)

Establishment

Name	Address	ID/FEI	Business Operations
Dispensing Solutions, Inc.		066070785	relabel, repack

Revised: 10/2011

Dispensing Solutions, Inc.