

**ROBAFEN COUGH NON-DROWSY FORMULA- dextromethorphan hbr capsule, liquid filled  
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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**Rugby 44-661**

***Active ingredient (in each liquid-filled capsule)***

Dextromethorphan HBr, USP 15 mg

***Purpose***

Cough suppressant

***Use***

temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold

***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 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

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

- a cough that occurs with too much phlegm (mucus)
- a cough that lasts or is chronic as occurs with smoking, asthma, or emphysema

**Stop use and ask a doctor if**

cough lasts for more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.

**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 (1-800-222-1222) right away.

***Directions***

- do not take more than 8 capsules in any 24-hour period
- this adult product is not intended for use in children under 12 years of age
- adults and children 12 years and over: take 2 capsules every 6 to 8 hours, as needed
- children under 12 years: do not use

***Other information***

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- avoid excessive heat above 40°C (104°F)
- protect from light
- see bottle for lot number and expiration date

***Inactive ingredients***

edible white ink, FD&C blue #1, FD&C red#40, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol

***Questions or comments?***

**1-800-645-2158**

**Principal display panel**

***Rugby***<sup>®</sup>

NDC 0536-1068-34

\*Compare to the active ingredient in Robitussin<sup>®</sup> Long-Acting CoughGels<sup>®</sup>

***Non-Drowsy Formula***

**ROBAFEN<sup>®</sup> COUGH**

**LIQUIDGELS**

**Dextromethorphan HBr, USP 15 mg**

***Cough Suppressant***

**8-Hour Cough Relief**

Easy-to-Swallow

Liquid-Filled

Capsules

**20**

**Liquidgels**

(Liquid-Filled

Capsules)

Distributed by:

**Rugby Laboratories**

**31778 Enterprise Drive**

**Livonia, MI 48150**

**[www.rugbylaboratories.com](http://www.rugbylaboratories.com)**

R-17

Rev. 05/19

Re-Order No. 370416

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

\*This product is not manufactured or distributed by Wyeth LLC, owner of the registered trademark Robitussin<sup>®</sup> Long-Acting CoughGels<sup>®</sup>.

50844 REV0319B66109

Product of China

Packaged and

Quality Assured  
in the USA

**Rugby**®

NDC 0536-1068-34  
Compare to the active ingredient in Robitussin® Long-Acting CoughGels®

**Non-Drowsy Formula**

**ROBAFEN® COUGH LIQUIDGELS**

Dextromethorphan HBr, USP 15 mg  
Cough Suppressant

**8-Hour Cough Relief**

Easy-to-Swallow Liquid-Filled Capsules

**20 Liquidgels**  
(Liquid-Filled Capsules)

Distributed by:  
Rugby Laboratories  
17177 N Laurel Park Drive  
Suite 233  
Livonia, MI 48152  
www.rugbylaboratories.com  
R-17  
Rev. 05/19  
Re-Order No. 370416

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**Drug Facts**

**Active ingredient (in each liquid-filled capsule)** Dextromethorphan HBr, USP 15 mg  
**Purpose** Cough suppressant

**Use** temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold

**Warnings**  
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Ask a doctor before use if you have  
■ a cough that occurs with too much phlegm (mucus)  
■ a cough that lasts or is chronic as occurs with smoking, asthma, or emphysema  
**Stop use and ask a doctor** if cough lasts for more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.  
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1-800-645-2158

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44-661

**ROBAFEN COUGH NON-DROWSY FORMULA**

dextromethorphan hbr capsule, liquid filled

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0536-1068
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg

### Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

### Product Characteristics

Color	RED (clear)	Score	no score
Shape	OVAL	Size	10mm
Flavor		Imprint Code	661
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1068-34	1 in 1 PACKAGE	03/01/2015	
1		20 in 1 BOTTLE; 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	03/01/2015	

**Labeler** - Rugby Laboratories (079246066)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(0536-1068)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(0536-1068)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(0536-1068)

Revised: 6/2019

Rugby Laboratories