

**EXTRA ACTION COUGH- guaifenesin and dextromethorphan hydrobromide liquid**  
**Rugby Laboratories 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.*

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**Rugby®**

**EXTRA**

**ACTION**

**Cough**

**SYRUP**

***Drug Facts***

<b><i>Active ingredients (in each 2 teaspoonfuls (10 mL))</i></b>	<b><i>Purposes</i></b>
Dextromethorphan HBr USP 20 mg	Cough Suppressant
Guaifenesin USP 200 mg	Expectorant

**Uses**

- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes

**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**

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

**Stop use and ask a doctor if** cough lasts more than 7 days, comes back, or is accompanied by fever, rash or headache that lasts. 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 right away.

### **Directions**

- do not take more than 6 doses in any 24-hour period
- this product is not intended for use in children under 12 years of age

adults and children 12 years and over	2 teaspoonfuls every 4 hours
children under 12 years	<b>do not use</b>

### **Other information**

- each teaspoonful (5mL) contains: **sodium 3 mg**
- store at 20°- 25°C (68°- 77°F) . Do not refrigerate.

### **Inactive Ingredients**

Artificial cherry flavor, citric acid, corn syrup, FD&C Red #40, glycerin, menthol, purified water, saccharin sodium, sodium benzoate.

### **Questions or comments?**

**1-800-645-2158**

### **Distributed by:**

**Rugby Laboratories  
17177 N Laurel Park Drive,  
Suite 233  
Livonia, MI 48152 USA**

### **PRINCIPAL DISPLAY PANEL - 473 mL Bottle Label**

**COMPARE TO  
ACTIVE INGREDIENTS IN  
ROBITUSSIN<sup>®</sup> COLD COUGH+CHEST  
CONGESTION DM\***

**Rugby<sup>®</sup>**

**NDC 0536-0970-85**

Non-narcotic Cough Suppressant  
and Expectorant

### **EXTRA ACTION**

### **Cough Syrup**

(Guaifenesin with  
Dextromethorphan HBr Syrup)

**TAMPER EVIDENT: DO NOT USE IF  
INNER FOIL SEAL OVER MOUTH OF  
BOTTLE IS BROKEN OR MISSING**

**This is a bulk package, not intended for households**

**with young children. Dispense contents with a child-resistant closure in a tight, light-resistant container as defined in the USP.**

\*Rugby Laboratories is not affiliated with the owner  
ROBITUSSIN<sup>®</sup> COLD COUGH+CHEST CONGESTION DM

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**17177 N Laurel Park Drive,**

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**Livonia, MI 48152 USA**

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

**One Pint (473 mL)**

**Re-order No. 370054**

**Rev. 03/17**

**R-64**

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# Rugby®

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Re-order No. 370054  
Rev. 03/17 R-64

unvarnished area

LOT/EXP

## EXTRA ACTION COUGH

guaifenesin and dextromethorphan hydrobromide liquid

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-0970
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 5 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>CORN SYRUP</b> (UNII: 9G5L16BK6N)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>MENTHOL, UNSPECIFIED FORM</b> (UNII: L7T10EIP3A)	
<b>CHERRY</b> (UNII: BUC5I9595W)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	

### Product Characteristics

<b>Color</b>	pink (Reddish-Pink)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MENTHOL, CHERRY	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-0970-97	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/03/2011	03/30/2020
2	NDC:0536-0970-85	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/03/2011	05/31/2020

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	02/03/2011	05/31/2020

**Labeler** - Rugby Laboratories Inc. (079246066)