

**MUCUS RELIEF- guaifenesin tablet, extended release**  
**Rugby Laboratories**

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**Drug Facts**

**Active ingredient (in each extended-release tablet)**

Guaifenesin 1200 mg

**Purpose**

Expectorant

**Uses**

Helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and makes coughs more productive.

**Warnings**

**Do not use**

for children under 12 years of age.

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

- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema
- cough accompanied by too much phlegm (mucus)

**Stop use and ask a doctor if**

cough lasts more than 7 days, comes back, or occurs with fever, rash or persistent headache. These could be signs of a serious illness.

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

**Directions**

- do not crush, chew, or break tablet
- take with a full glass of water
- this product can be administered without regard for the timing of meals

- adults and children 12 years of age and over: 1 tablet every 12 hours. Do not exceed 2 tablets in 24 hours.
- children under 12 years of age: do not use

### **Other information**

- store between 20° to 25°C (68° to 77°F)

### **Inactive ingredients**

carbomer, colloidal silicon dioxide, FD&C blue #1 aluminum lake, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone, talc

### **Questions or comments?**

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

### **Principal Display Panel**

compare to the active ingredient in Maximum Strength Mucinex®\*

Maximum strength

Guaifenesin

Extended-Release

guaifenesin, 1200 mg

Expectorant

1200 mg

- 12-hour relief
- Relieves chest congestion
- Thins and loosens mucus

Extended-Release Tablets

\*This product is not manufactured or distributed by Reckitt Benckiser LLC, distributor of Maximum Strength Mucinex®.

**TAMPER EVIDENT: DO NOT USE IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.**

**KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.**

Distributed by:

RUGBY® LABORATORIES

Indianapolis, IN 46268

### **Package Label**

<b>Drug Facts</b>	
<b>Active ingredient</b> (in each extended-release tablet)	<b>Purpose</b>
Guaifenesin 1200 mg.....	Expectorant
<b>Uses</b> Helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive.	
<b>Warnings</b> Do not use for children under 12 years of age.	
<b>Ask a doctor before use if you have</b>	
<ul style="list-style-type: none"> <li>■ persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema</li> <li>■ cough accompanied by too much phlegm (mucus)</li> </ul>	
<b>Stop use and ask a doctor</b> if cough lasts more than 7 days, comes back, or occurs with fever, rash or persistent headache. These could be signs of a serious illness.	
<b>If pregnant or breast-feeding</b> , ask a health professional before use.	
<b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>■ do not crush, chew, or break tablet</li> <li>■ take with a full glass of water</li> <li>■ this product can be administered without regard for the timing of meals</li> <li>■ adults and children 12 years of age and over: 1 tablet every 12 hours. Do not exceed 2 tablets in 24 hours.</li> <li>■ children under 12 years of age: do not use</li> </ul>	
<b>Other information</b>	
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<b>Inactive ingredients</b> carbomer, colloidal silicon dioxide, FD&C blue #1 aluminum lake, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone, talc	
<b>Questions or comments?</b> Call 1-877-753-3935 Monday-Friday 9AM-5PM EST	

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Distributed by:  
**RUGBY® LABORATORIES**  
Indianapolis, IN 46268  
(800) 616-2471  
www.major-rugby.com

Product of India

Rev. 01/25 R-58 Re-order No. 371155



NDC 0536-1392-88

maximum strength  
guaifenesin ER



NDC 0536-1392-88

compare to the active ingredient in Maximum Strength Mucinex®\*

maximum strength  
**guaifenesin ER**

guaifenesin, 1200 mg  
expectorant

- 12-hour relief
- relieves chest congestion
- thins and loosens mucus



actual size

14 extended-release tablets

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KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

PLD-B518A FC009156

Lot No.:

Exp. Date:

**RUGBY Maximum Strength Guaifenesin ER**

## MUCUS RELIEF

guaifenesin tablet, extended release

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0536-1392(NDC:65162-037)
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	1200 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	

<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>CARBOMER 934</b> (UNII: Z135WT9208)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	

### Product Characteristics

<b>Color</b>	blue	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	22mm
<b>Flavor</b>		<b>Imprint Code</b>	AN037
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1392-88	14 in 1 CARTON	07/01/2023	10/28/2026
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207342	07/01/2023	10/28/2026

**Labeler** - Rugby Laboratories (079246066)

Revised: 2/2026

Rugby Laboratories