

MUCUS RELIEF EXTENDED RELEASE- guaifenesin tablet, extended release
Rugby Laboratories, Inc.

Drug Facts

Active ingredient (in each extended-release tablet)

Guaifenesin 600 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 or 2 tablet every 12 hours. Do not exceed 4 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 Mucinex®*

guaifenesin ER

Guaifenesin 600 mg

Expectorant

- 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 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 i

INDIANAPOLIS, IN 46268

Package Label

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Uses Helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive.	
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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. 370666



NDC 0536-1163-61

guaifenesin ER



NDC 0536-1163-61

compare to the active ingredient in Mucinex®*

guaifenesin ER

guaifenesin, 600 mg
expectorant

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



100 extended-release tablets

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KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

PLD-C517A FC009170

Lot No.:
Exp. Date:

RUGBY Extended-Release Tablets

MUCUS RELIEF EXTENDED RELEASE

guaifenesin tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1163
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	600 mg

Inactive Ingredients

Ingredient Name	Strength
CARBOMER 934 (UNII: Z135WT9208)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	blue	Score	no score
Shape	OVAL	Size	16mm
Flavor		Imprint Code	AN036
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1163-61	100 in 1 CARTON	08/31/2018	
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	08/31/2018	

Labeler - Rugby Laboratories, Inc. (079246066)

Revised: 4/2025

Rugby Laboratories, Inc.