

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

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

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

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Warnings Do not use for children under 12 years of age. Ask a doctor before use if you have <ul style="list-style-type: none"> ■ 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).	
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Distributed by:
RUGBY® LABORATORIES
 Indianapolis, IN 46268
 Questions or comments?
 Call (800) 616-2471
 www.majorpharmaceuticals.com



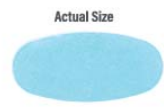
Maximum Strength
Guaifenesin
Extended-Release
Expectorant
1200 mg



NDC 0536-1392-88
 Compare to the active ingredient in
 Maximum Strength Mucinex®

Maximum Strength
Guaifenesin
Extended-Release
Expectorant
1200 mg

- 12-Hour Relief
- Relieves chest congestion
- Thins and loosens mucus



14 Extended-Release Tablets

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KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.
 PLD-A518A FC008710
 Lot No.:
 Exp. Date:

RUGBY Maximum Strength Mucus Relief

MUCUS RELIEF			
guaifenesin tablet, extended release			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1392(NDC:65162-037)
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	1200 mg
Inactive Ingredients			
	Ingredient Name		Strength
	SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		

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

Product Characteristics

Color	blue	Score	no score
Shape	OVAL	Size	22mm
Flavor		Imprint Code	AN037
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1392-88	14 in 1 CARTON	07/01/2023	
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	

Labeler - Rugby Laboratories, Inc. (079246066)

Revised: 6/2023

Rugby Laboratories, Inc.