MUCUS RELIEF EXTENDED RELEASE MAXIMUM STRENGTH- guaifenesin tablet QUALITY CHOICE (Chain Drug Marketing Association)

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 **1-248-449-9300** Monday-Friday 9AM-5PM EST

Principal Display Panel

Compare to the Active Ingredient in Maximum Strength Mucinex®

Maximum Strength

Mucus Relief

Guaifenesin

Extended Release

Tablets 1200 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 Maximum Strength Mucinex $^{\circ}$.

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 C.D.M.A., Inc.©

43157 W 9 Mile Rd

Novi. MI 48375

www.qualitychoice.com

Package Label



QUALITY CHOICE Maximum Strength Mucus Relief

Lot No.:

MUCUS RELIEF EXTENDED RELEASE MAXIMUM STRENGTH

guaifenesin tablet					
Product Information					
Product Type	HUMAN OTC DRUG	Item Code (S	ource)	NDC:638	368-872
Route of Administration	ORAL				
A ation to our disort/A ation	No. to Ann.				
Active Ingredient/Active Moiety					
Ingredient Name		Basis of Strength		Strength	
GUAIFENESIN (UNII: 495W7451VQ)	(GUAIFENES IN - UNII:495W	7451VQ)	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				

F	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:63868-872- 14	14 in 1 CARTON	12/31/2018	12/31/2025			
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	12/31/2018	12/31/2025	

Labeler - QUALITY CHOICE (Chain Drug Marketing Association) (011920774)

Revised: 5/2023 QUALITY CHOICE (Chain Drug Marketing Association)