MUCUS RELIEF EXTENDED RELEASE MAXIMUM STRENGTH- guaifenes in tablet Cardinal Health (Leader) 70000

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 MUCINEX® MAXIMUM STRENGTH active ingredient*

Maximum Strength

Mucus Relief

Guaifenesin, 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®.

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

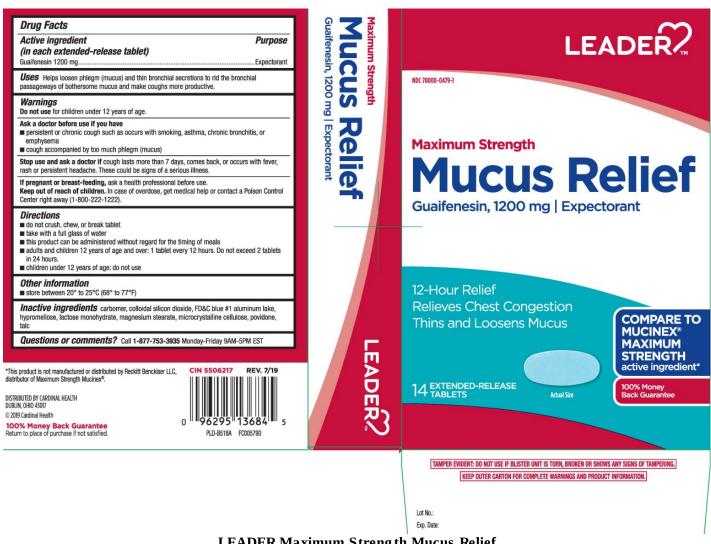
KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

DISTRIBUTED BY CARDINAL HEALTH

DUBLIN OHIO 43017

www.myleader.com

Package Label



LEADER Maximum Strength Mucus Relief

MUCUS RELIEF EXTENDED RELEASE MAXIMUM STRENGTH

MAGNESIUM STEARATE (UNII: 70097M6I30)

CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)

CARBOMER 934 (UNII: Z135WT9208)

guaifenesin tablet					
Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source) NDC:70000-04		0-0479	
Route of Administration	ORAL				
Active Ingredient/Active Moiety					
Ingredient Name Basis of Stren			Strength	Strength	
GUAIFENESIN (UNII: 495W7451VQ) (G	GUAIFENES IN - UNII:495W7451V	/Q)	GUAIFENESI	N	1200 mg
Inactive Ingredients					
	Ingredient Name			:	Strength
SILICON DIO XIDE (UNII: ETJ7Z6 XBU	(4)				

PO VIDO NE (UNII: FZ989 GH94E)	
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				

P	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:70000-0479-1	14 in 1 CARTON	0 1/3 1/20 19				
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product					
2	NDC:70000-0479-2	28 in 1 CARTON	0 1/3 1/20 19				
2		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	0 1/3 1/2 0 19			

Labeler - Cardinal Health (Leader) 70000 (097537435)

Revised: 7/2019 Cardinal Health (Leader) 70000