

MUCUS RELIEF EXTENDED RELEASE MAXIMUM STRENGTH- guaifenesin 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

guaifenesin tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0479
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 DIO XIDE (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:70000-0479-1	14 in 1 CARTON	01/31/2019	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:70000-0479-2	28 in 1 CARTON	01/31/2019	
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		01/31/2019	

Labeler - Cardinal Health (Leader) 70000 (097537435)