MUCUS RELIEF- guaifenesin tablet P & L Development, LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active ingredient (in each tablet)

Guaifenesin 400 mg

Purpose

Expectorant

Uses

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

Warnings

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 condition.

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 exceed 6 tablets in 24 hours
- take with a full glass of water
- adults and children 12 years of age and older:

- take 1 tablet every 4 hours while symptoms persist.
- children under 12 years of age: do not use

Other information

- each tablet contains: sodium 5 mg
- store between 20-25°C (68-77°F)

Inactive ingredients

colloidal silicon dioxide, magnesium stearate, maltodextrin, microcrystalline cellulose, povidone, sodium starch glycolate, stearic acid

Questions or comments?

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

Principal Display Panel

Immediate Acting Mucus Relief

Guaifenesin 400 mg

Expectorant

- Relieves Chest Congestion
- Thins and Loosens Mucus

Tablets

Distributed by:

PL Developments

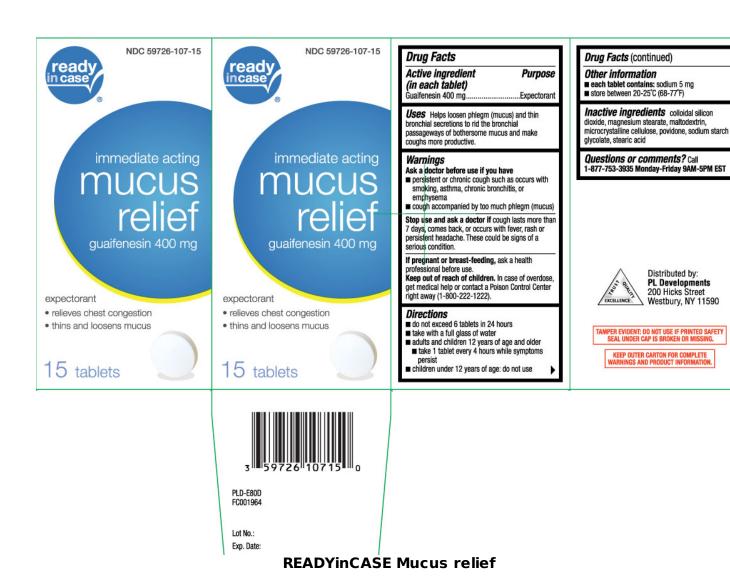
200 Hicks Street

Westbury, NY 11590

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Product Label



MUCUS RELIEF

guaifenesin tablet

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:59726-107 Route of Administration ORAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) GUAIFENESIN (UNII: 495W7451VQ)

Inactive Ingredients			
Ingredient Name	Strength		
SILICON DIOXIDE (UNII: ETJ7Z 6XBU4)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
MALTODEXTRIN (UNII: 7CVR7L4A2D)			
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)			

POVIDONE (UNII: FZ989GH94E)

SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)

STEARIC ACID (UNII: 4ELV7Z65AP)

Product Characteristics						
Color	white	Score	2 pieces			
Shape	ROUND	Size	13mm			
Flavor		Imprint Code	TCL272;G1			
Contains						

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:59726- 107-15	1 in 1 BOX	12/07/2012	04/26/2024		
1		15 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product				
2	NDC:59726- 107-30	1 in 1 BOX	12/07/2012	04/26/2024		
2		30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	12/07/2012	04/26/2024	

Labeler - P & L Development, LLC (800014821)

Revised: 10/2021 P & L Development, LLC