

GUAIFENESIN- guaifenesin tablet
Reliable 1 Laboratories 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.

Guifenisen 400 mg

Drug Facts

Active ingredient (in each caplet)

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 is accompanied by fever, rash, or persistent headache. These could be signs of serious illness.

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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.

Directions

- do not take more than 6 doses in any 24- hour period
- this product is not intended for use in children under 12 years of age

- adults & children 12 years and over: 1 caplet every 4 hours
- children under 12 years: do not use

Other information

store at 15°-30°C (59°-86°F)

Inactive ingredients

colloidal silicon dioxide, magnesium stearate, maltodextrin, microcrystalline cellulose, providone, stearic acid

Questions or comments?

call 516-341-0666, 8:30 am-4:30 pm ET, Monday-Friday

Drug Facts *continued on back of label*

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

Distributed by: **Reliable-1 Laboratoreis LLC**

Valley Stream, Ny 11580 www.reliable1labs.com

NDC 69618-061-06

Reliable-1 Laboratories

Guaifenesin 400 mg

Expectorant

60 CAPLETS

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400 mg
EXPECTORANT

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LA0420
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Lot No.:
Exp. Date:

FRONT

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GUAIFENESIN

guaifenesin tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69618-061
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	

Product Characteristics

Color	white	Score	no score
Shape	OVAL	Size	17mm
Flavor		Imprint Code	A;152
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69618-061-06	60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/01/2020	

Labeler - Reliable 1 Laboratories LLC (079718111)

Registrant - Reliable 1 Laboratories LLC (079718111)

Revised: 3/2023

Reliable 1 Laboratories LLC