

**GUAIFENESIN- guaifenesin tablet, extended release
GRANULES PHARMACEUTICALS INC.**

Guaifenesin Extended-Release Tablets 600mg and 1200mg

ACTIVE INGREDIENT(S)

Guaifenesin 600 mg (for 600mg)

PURPOSE

Expectorant

USE(S)

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make 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 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 timing of meals
- adults and children 12 years of age and over: 1 or 2 tablets every 12 hours. Do not exceed 4 tablets in 24 hours(For 600mg)
- children under 12 years of age: do not use

OTHER INFORMATION

- **do not use if foil inner seal is broken or missing.**
- store between 20-25°C (68-77°F)

INACTIVE INGREDIENTS

carbomer homopolymer type B; hypromellose, magnesium stearate, microcrystalline cellulose, sodium starch glycolate

QUESTIONS OR COMMENTS

Contact 1-877-770-3183
Mon-Fri 8:00 AM EST to 5:00 PM PST.

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PRINCIPAL DISPLAY PANEL

NDC 70010-199-05 *Compare to the active ingredient of Mucinex®

Guaifenesin Extended-Release Tablets

12
HR

600 mg

Expectorant

- Relieves Chest Congestion
- Thins and Loosens Mucus
- Immediate and Extended Release

500
EXTENDED-RELEASE
BI-LAYER TABLETS

Important: Read all directions and warnings before use.
DANGER: DO NOT USE IF IMPRINTED FOIL INNER SEAL ON BOTTLE IS BROKEN OR MISSING

Drug Facts

Active ingredient (in each extended-release bi-layer tablet) Guaifenesin 600 mg, Extended-Release Expectoant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make 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 has more than 7 days, worse back, or occurs with fever, rash, or persistent headache.
- you are still coughing after 7 days.

Keep out of reach of children. Ask a health professional before use.

Directions

- do not crush, chew, or break tablet
- use with a full glass of water
- take with or without food, without regard for timing of meals
- adults and children 12 years of age and over: 1 or 2 tablets every 12 hours. Do not exceed 4 tablets in 24 hours
- children under 12 years of age: do not use

Other information

- Do not use if foil inner seal is broken or missing
- store between 20-25°C (68-77°F)

Inactive ingredients

carbomer homopolymer type B, hypromellose, magnesium stearate, microcrystalline cellulose, sodium starch glycolate

Questions?

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Distributed by:
Glenmark Pharmaceuticals Inc.,
Charlottesville, VA 20151
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MADE IN INDIA

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GUAIFENESIN

guaifenesin tablet, extended release

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:70010-199

Route of Administration	ORAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	600 mg	
Inactive Ingredients				
	Ingredient Name	Strength		
	SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)			
	MAGNESIUM STEARATE (UNII: 70097M6I30)			
	CARBOMER HOMOPOLYMER TYPE B (ALLYL SUCROSE CROSSLINKED) (UNII: Z135WT9208)			
	MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			
	HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)			
	HYPROMELLOSE 2910 (10000 MPA.S) (UNII: 0HO1H52958)			
Product Characteristics				
Color	white	Score	no score	
Shape	OVAL	Size	16mm	
Flavor		Imprint Code	G;600	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70010-199-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	08/19/2022	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA213420	08/19/2022		

Labeler - GRANULES PHARMACEUTICALS INC. (079825711)

Revised: 1/2023

GRANULES PHARMACEUTICALS INC.