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)

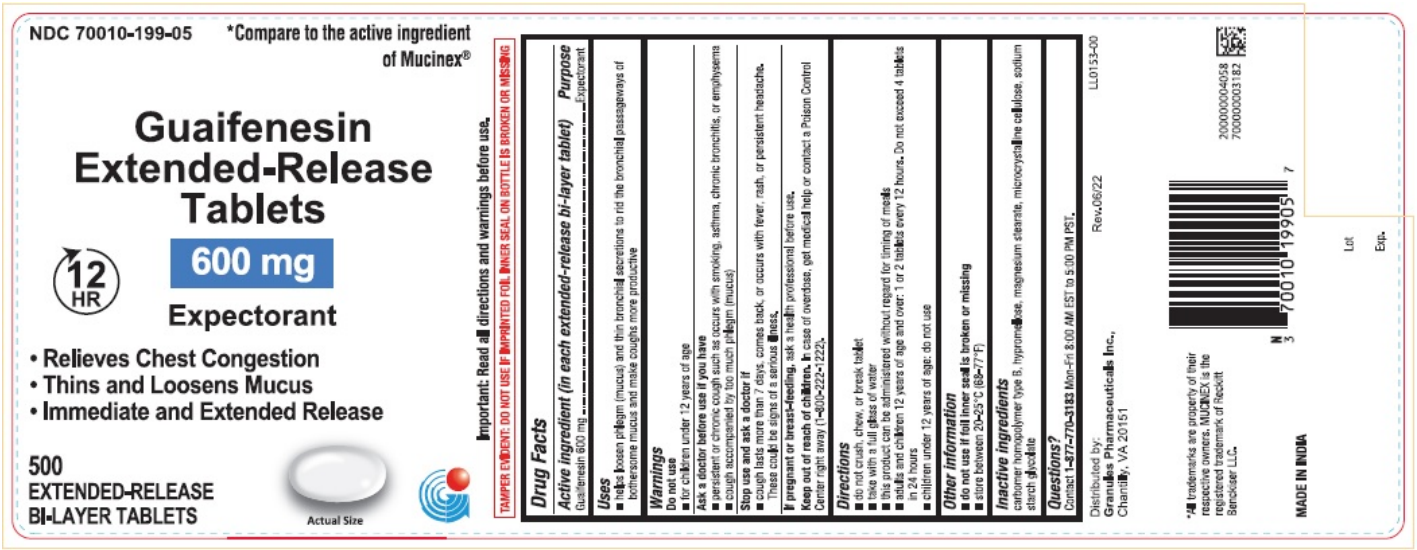
INACTIVE INGREDIENTS

carbomer homopolymer type B; hypromellos, 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.

PRINCIPAL DISPLAY PANEL



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.