GUAIFENESIN- guaifenesin tablet, extended release
GRANULES USA, INC.

Guaifenesin
Extended-Release Tablets 600 mg
Expectorant
12 HR

Active ingredients (in each extended-release bi-layer tablet)

Guaifenesin 600 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

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 breat-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
■ children under 12 years of age: do not use

Other information

■ **Tamper evident: Do not use if carton is open or if printed seal on blister 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?

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

PDP

GUAIFENESIN

guaifenesin tablet, extended release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69848-017
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**
CARBOMER HOMOPOLYMER TYPE B (ALLYL SUCROSE CROSSLINKED) (UNII: Z135WT9208)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

MAGNESIUM STEARATE (UNII: 70097M6I30)	

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:69848-017-02	20 in 1 BLISTER PACK; Type 0: Not a Combination Product	01/06/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA213420	12/31/2021	

Labeler - GRANULES USA, INC. (137098864)

Revised: 12/2023 GRANULES USA, INC.