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

Maximum Strength
Guaifenesin Extended-Release Tablets 1200 mg
Expectorant
• Relieves Chest Congestion
• Thins and Loosens Mucus
• Immediate and Extended Release

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

Guaifenesin 1200 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 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 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 tablet every 12 hours. Do not exceed 2 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, hypromellose, magnesium stearate, microcrystalline cellulose, sodium starch glycolate

Questions?

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:69848-018
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	1200 mg

Inactive Ingredients	
Ingredient Name	**Strength**
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL SUCROSE CROSSLINKED) (UNII: Z135WT9208)	

Product Characteristics			
Color	white	**Score**	no score
Shape	OVAL	**Size**	22mm
Flavor		**Imprint Code**	G;1200
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69848-018-16	14 in 1 BLISTER PACK; Type 0: Not a Combination Product	09/12/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA213420	09/12/2024	

Labeler - GRANULES USA, INC. (137098864)

Revised: 12/2025 GRANULES USA, INC.