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

Maximum Strength
Guaifenesin Extended-Release Tablets 1200mg
Expectorant
Relievers Chest Congestion
This and Loosems Mucus
Immediate and Extended Releas e
12 Hour

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.

Maximum Strength Guaifenesin Extended-Release Tablets 1200mg

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

Product Characteristics			
Color	white	**Score**	no score
Shape	OVAL (elliptical shaped, biconvex tablet)	**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	02/21/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA213420	02/21/2021	

Labeler - GRANULES USA, INC. (137098864)

Revised: 1/2024 GRANULES USA, INC.