GUAIFENESIN- guaifenesin tablet, extended release
Advanced Rx LLC

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

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 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 (1-800-222-1222) right away.

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

- store between 20-25°C (68-77°F).
- **DO NOT USE IF PRINTED SEAL UNDER CAP IS MISSING OR DAMAGED.**

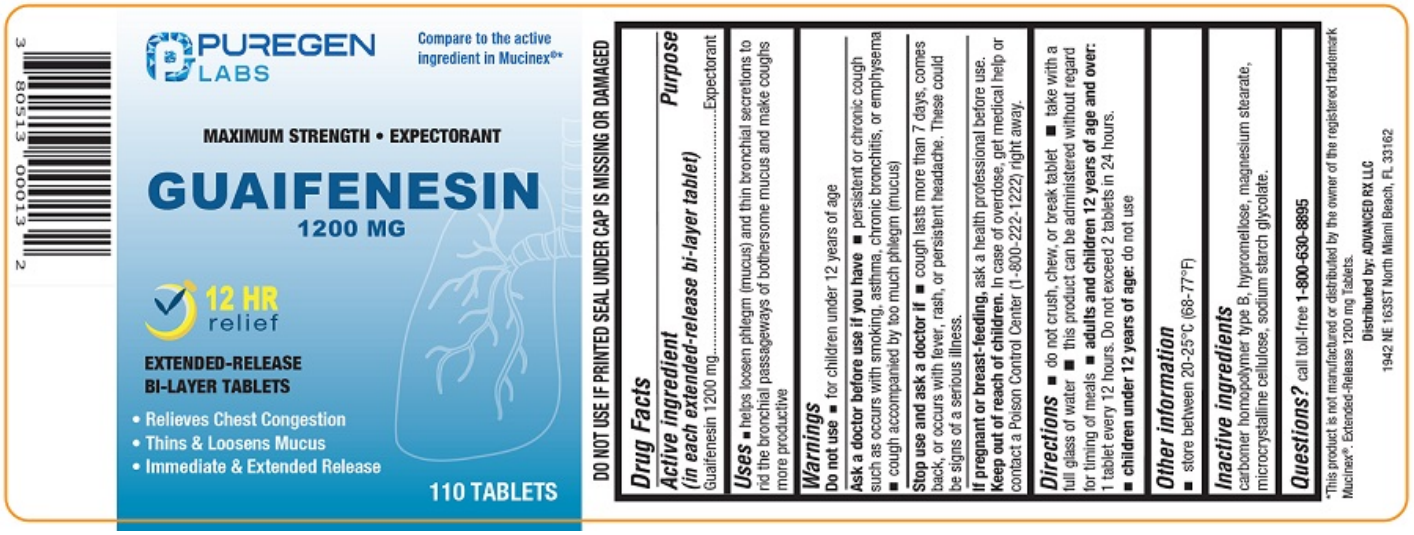
Inactive ingredients

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

Questions?

call toll-free **1-800-630-8895**

PRINCIPAL DISPLAY PANEL



GUAIFENESIN

guaifenesin tablet, extended release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:80513-413
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
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

Product Characteristics

Color	white	**Score**	no score
Shape	OVAL	**Size**	21mm
Flavor		**Imprint Code**	G;1200
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80513-413-11	110 in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA213420	12/18/2020	

Labeler - Advanced Rx LLC (042795108)

Establishment

Name	Address	ID/FEI	Business Operations
Ganules India Limited		918609236	manufacture(80513-413)

Revised: 7/2025 Advanced Rx LLC