

**GUAIFENESIN - guaifenesin tablet, extended release**  
**Aurohealth LLC**

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**Drug Facts**

**Active ingredient**

**(in each extended-release tablet)**

Guaifenesin USP 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

**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 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 the 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**

- store between 20° to 25°C (68° to 77°F)
- Tamper evident: Do not use if carton is open or if seal on blister is broken or missing

**Inactive ingredients**

colloidal silicon dioxide, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, and pregelatinised starch (maize)

**Questions?**

**1-855-274-4122** (Monday – Friday 8:30 AM to 5:00 PM EST) You may also report side effects to this phone number.

Distributed by:

**AUROHEALTH LLC**

279 Princeton-Hightstown Road  
East Windsor, NJ 08520

Made in India

Code: AP/DRUGS/04/2016

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 600 mg Blister Carton (100 (5 x 20) Tablets)**

NDC 58602-864-98

**PrimaryHealth**

**COMPARE TO** Mucinex®

Active Ingredient\*

**Guaifenesin**

**Extended-Release Tablets**

**600 mg**

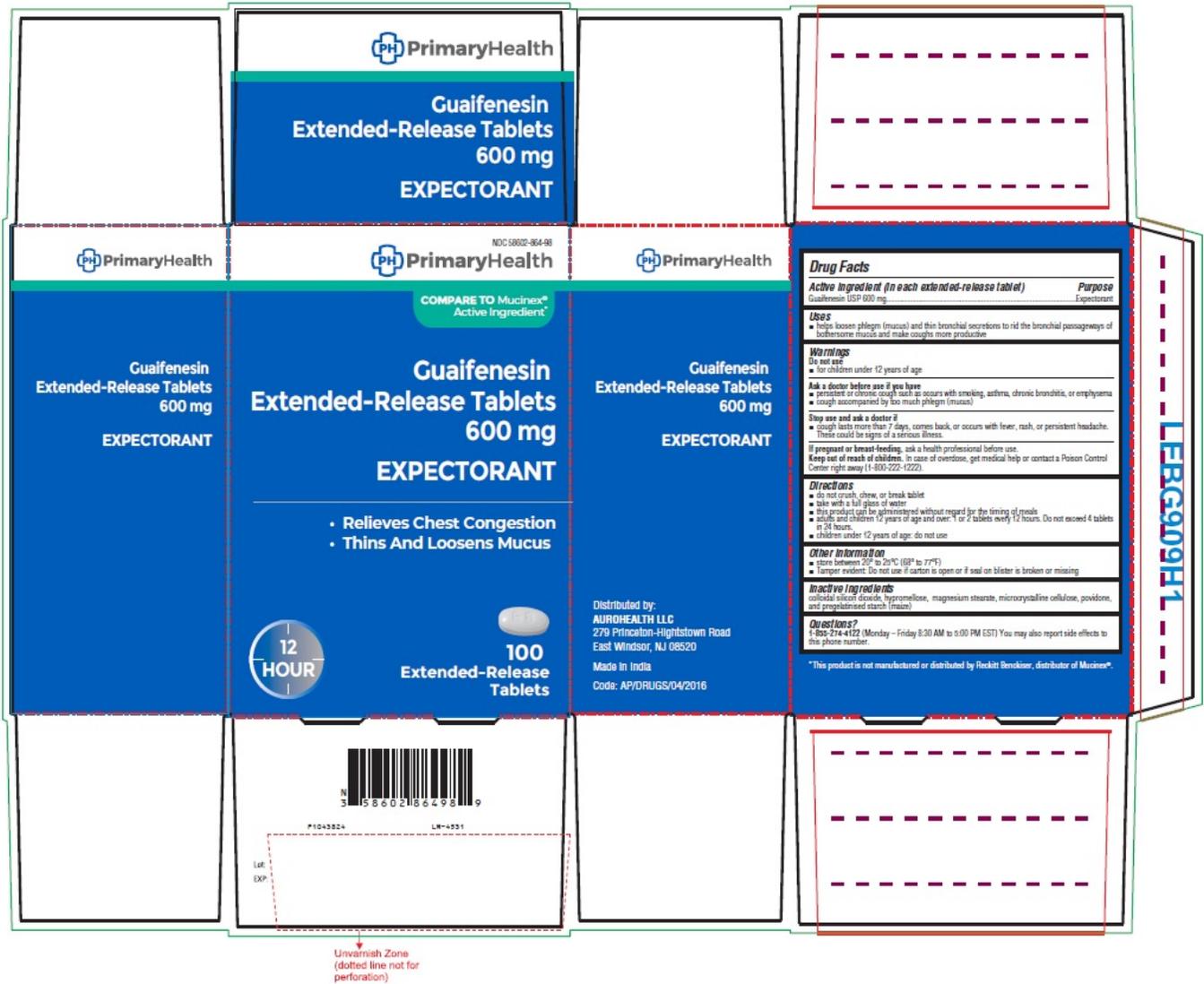
**EXPECTORANT**

- **Relieves Chest Congestion**

• Thins And Loosens Mucus

12  
HOUR

100  
Extended-Release  
Tablets



**GUAIFENESIN**

guaifenesin tablet, extended release

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58602-864
<b>Route of Administration</b>	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		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
HYPROMELLOSE 2208 (15000 MPA.S) (UNII: Z78RG6M2N2)				
HYPROMELLOSE 2910 (10000 MPA.S) (UNII: 0HO1H52958)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MICROCRYSTALLINE CELLULOSE 101 (UNII: 7T9FYH5QMK)				
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)				
POVIDONE K90 (UNII: RDH86HJV5Z)				
POVIDONE K25 (UNII: K0KQV10C35)				
STARCH, CORN (UNII: O8232NY3SJ)				
Product Characteristics				
Color	WHITE (white to off-white)	Score	no score	
Shape	OVAL	Size	16mm	
Flavor		Imprint Code	L;68	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-864-98	5 in 1 CARTON	03/11/2021	
1		20 in 1 BLISTER PACK; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA210453	03/11/2021		

**Labeler** - Aurohealth LLC (078728447)

### Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650918514	ANALYSIS(58602-864) , MANUFACTURE(58602-864)