GUAIFENESIN - guaifenesin tablet, extended release
Aurohealth LLC

Drug Facts

Active ingredient

(in each extended-release tablet)

Guaifenesin USP 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 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 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° 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 - 1200 mg Blister Carton (42 (3 x 14) Tablets)

NDC 58602-865-03
PrimaryHealth

COMPARE TO Maximum Strength Mucinex® Active Ingredient*

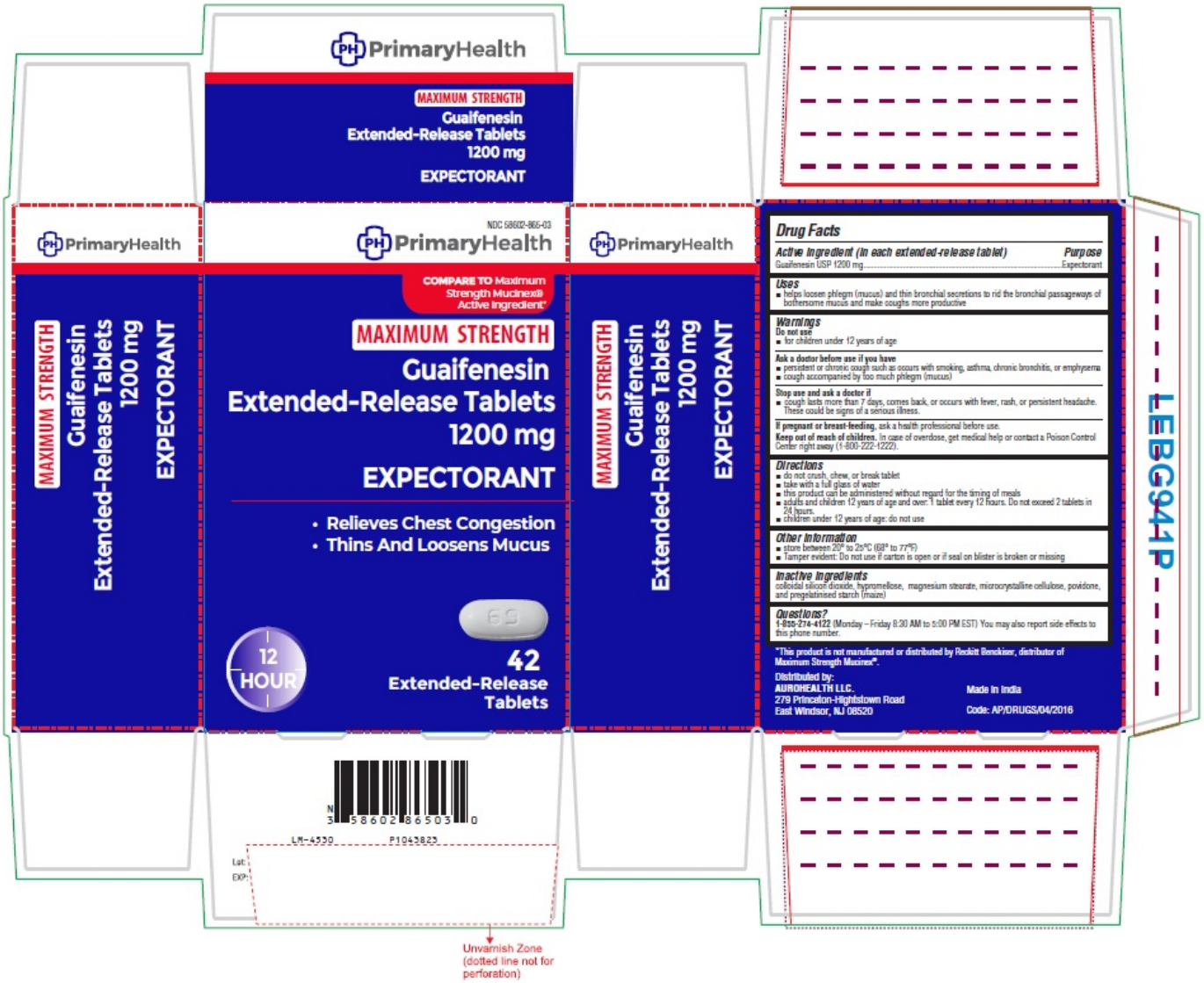
MAXIMUM STRENGTH

Guaifenesin
Extended-Release Tablets
1200 mg
EXPECTORANT

- **Relieves Chest Congestion**
- **Thins And Loosens Mucus**

12
HOUR

42
Extended-Release
Tablets



GUAIFENESIN

guaifenesin tablet, extended release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58602-865
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**
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**	21mm
Flavor		**Imprint Code**	L;69
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:58602-865-03	3 in 1 CARTON	03/11/2021	
1		14 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(58602-865) , MANUFACTURE(58602-865)

Revised: 12/2023 Aurohealth LLC