GUAIFENESIN - guaifenesin tablet, extended release
Aurohealth LLC

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)

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 (20 Tablet Label)

AUROHEALTH

NDC 58602-810-73

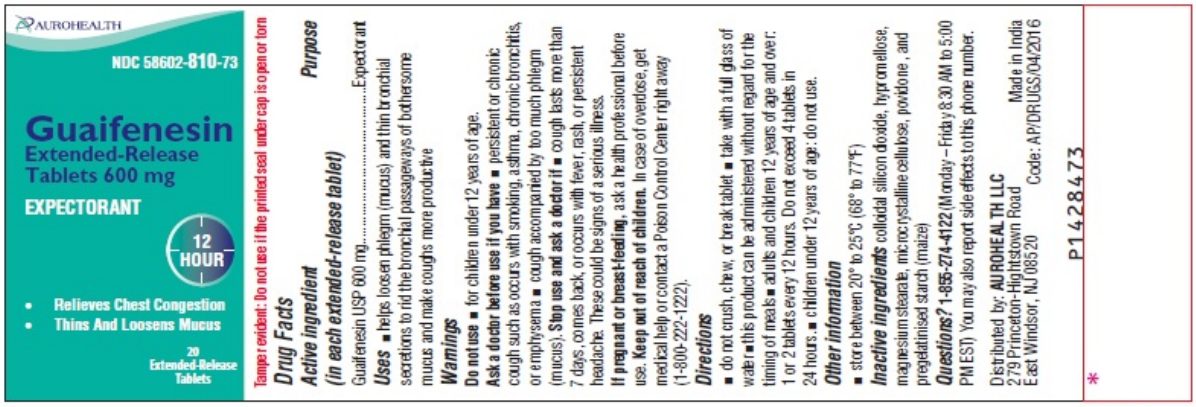
Guaifenesin
Extended-Release
Tablets 600 mg

EXPECTORANT

12 HOUR

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

20
Extended-Release
Tablets



* Lot: XXXXXXXXX
EXP: MM/YYYY
Prefix & Variables of Lot, EXP shall be printed online during packing.

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 600 mg (20 Tablet Carton Label)

AUROHEALTH

NDC 58602-810-73

Compare to the active
ingredient in Mucinex®*

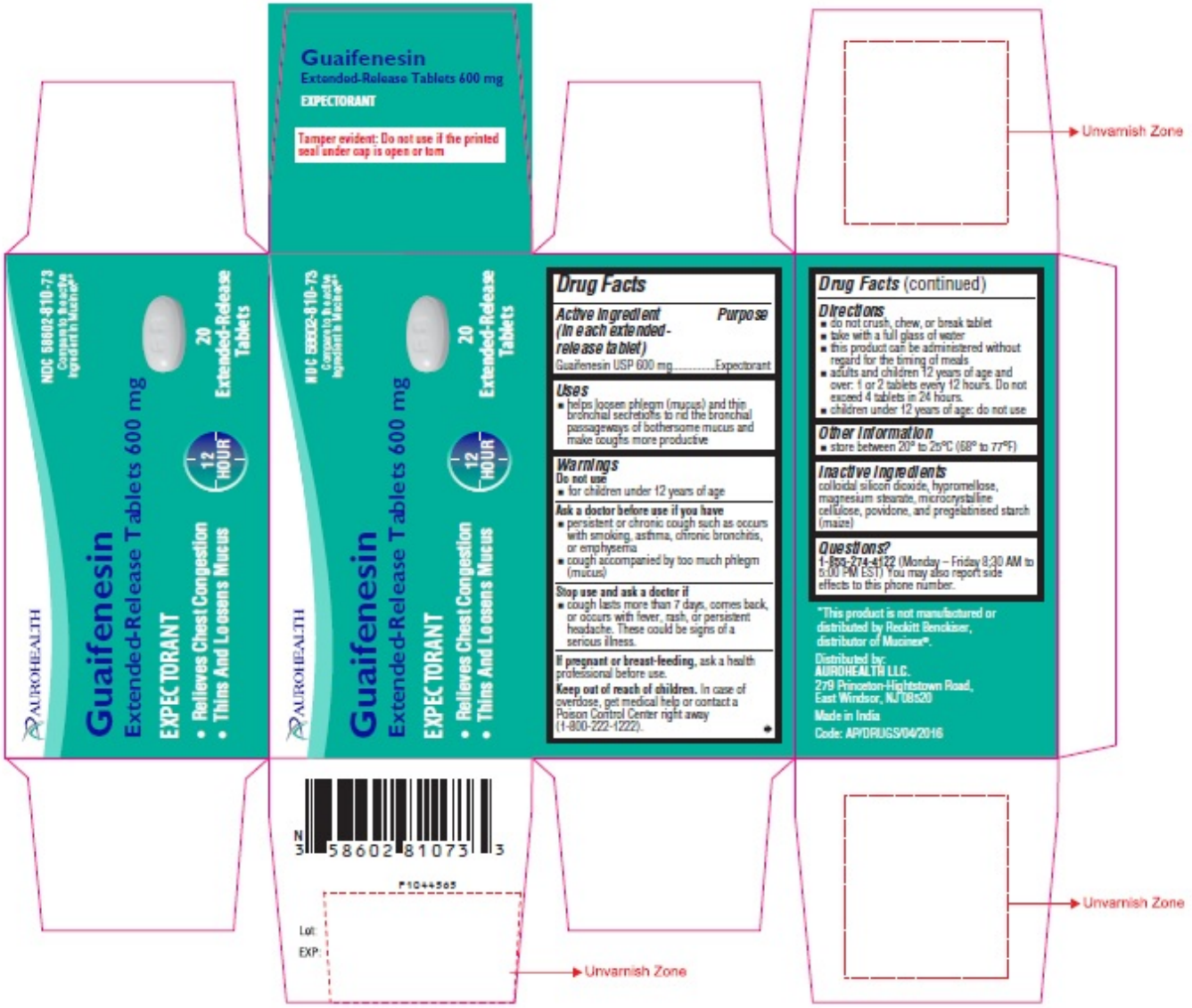
Guaifenesin
Extended-release Tablets 600 mg

EXPECTORANT

•Relieves Chest Congestion
•Thins And Loosens Mucus

12 HOUR

20 Extended Tablets



PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 600 mg Blister Carton (20 (1 x 20) Tablets)

AUROHEALTH

NDC 58602-810-96

Compare to the active
ingredient in Mucinex®*

Guaifenesin
Extended-release Tablets 600 mg

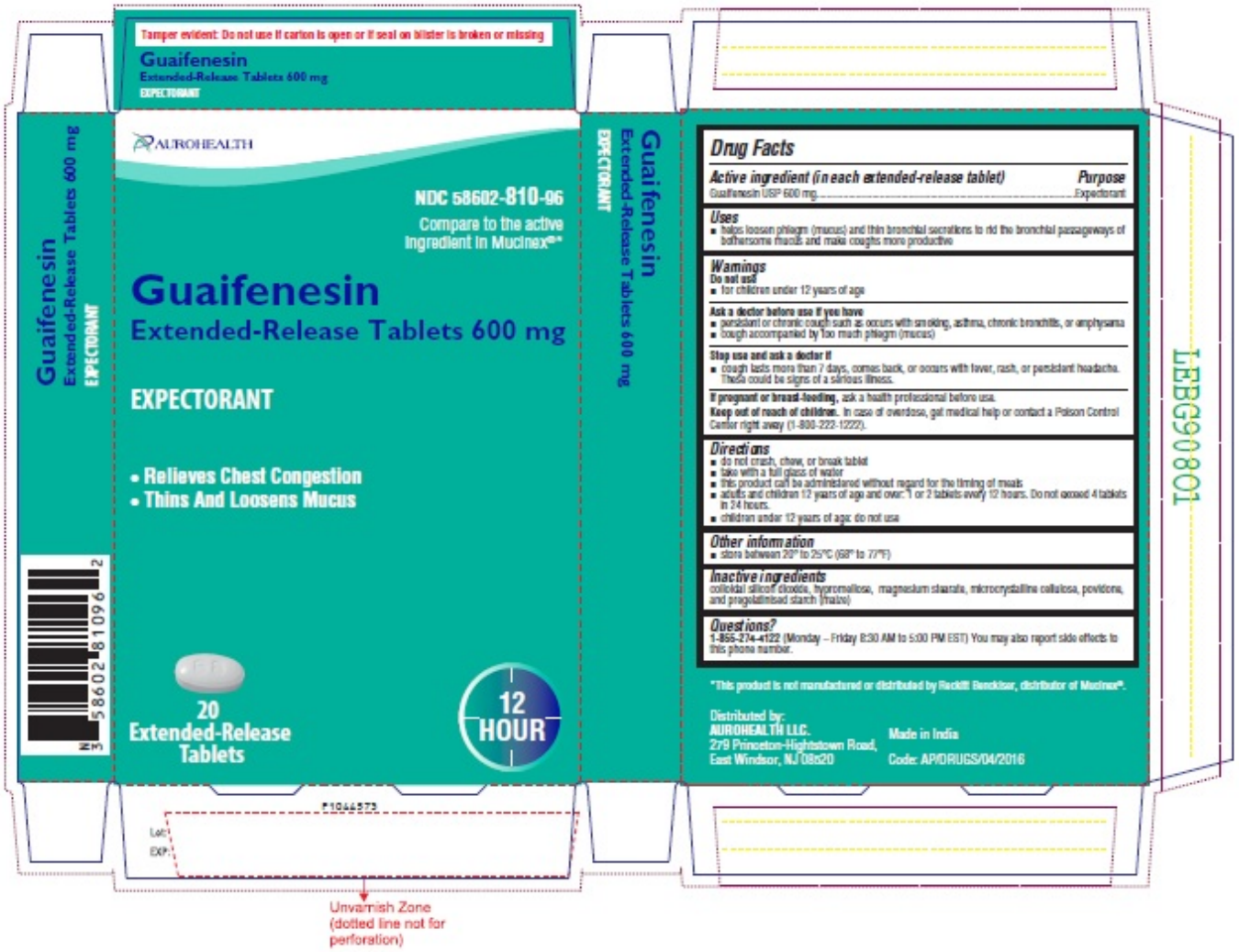
EXPECTORANT

•Relieves Chest Congestion
•Thins And Loosens Mucus

20
Extended-Release

Tablets

12 HOUR



GUAIFENESIN

guaifenesin tablet, extended release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58602-810
Route of Administration	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:58602-810-73	1 in 1 CARTON	10/21/2019	
1		20 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:58602-810-12	1 in 1 CARTON	10/21/2019	
2		40 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:58602-810-21	1 in 1 CARTON	10/21/2019	
3		100 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:58602-810-96	1 in 1 CARTON	10/21/2019	
4		20 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:58602-810-97	2 in 1 CARTON	10/21/2019	
5		20 in 1 BLISTER PACK; Type 0: Not a Combination Product		
6	NDC:58602-810-98	5 in 1 CARTON	10/21/2019	
6		20 in 1 BLISTER PACK; Type 0: Not a Combination Product		
7	NDC:58602-810-38	8 in 1 CARTON	12/07/2022	
7		10 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	10/21/2019	

Labeler - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650918514	ANALYSIS(58602-810) , MANUFACTURE(58602-810)

Revised: 12/2023 Aurohealth LLC