

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 extended-release 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 extended-release tablets every 12 hours. Do not exceed 4 extended-release 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)

Distributed by:

AUROHEALTH LLC.

279 Princeton-Hightstown Road,
East Windsor, NJ 08520

Made in India

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

AUROHEALTH

NDC 58602-810-73

**Guaifenesin
Extended-Release
Tablets 600 mg**

Guaifenesin 600 mg- Expectorant

RELIEVES CHEST CONGESTION

**12
HOUR**

- Relieves Chest Congestion
- Thins & Loosens Mucus

20 Extended-Release Tablets



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20 Extended-Release Tablets

Tamper Evident: Do not use if the printed seal under cap is open or torn

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P 1 4 3 5 3 1 7

* Unvarnished Zone
(dotted line not for printing)
40 x 12 mm

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

Guaifenesin 600 mg - Expectorant

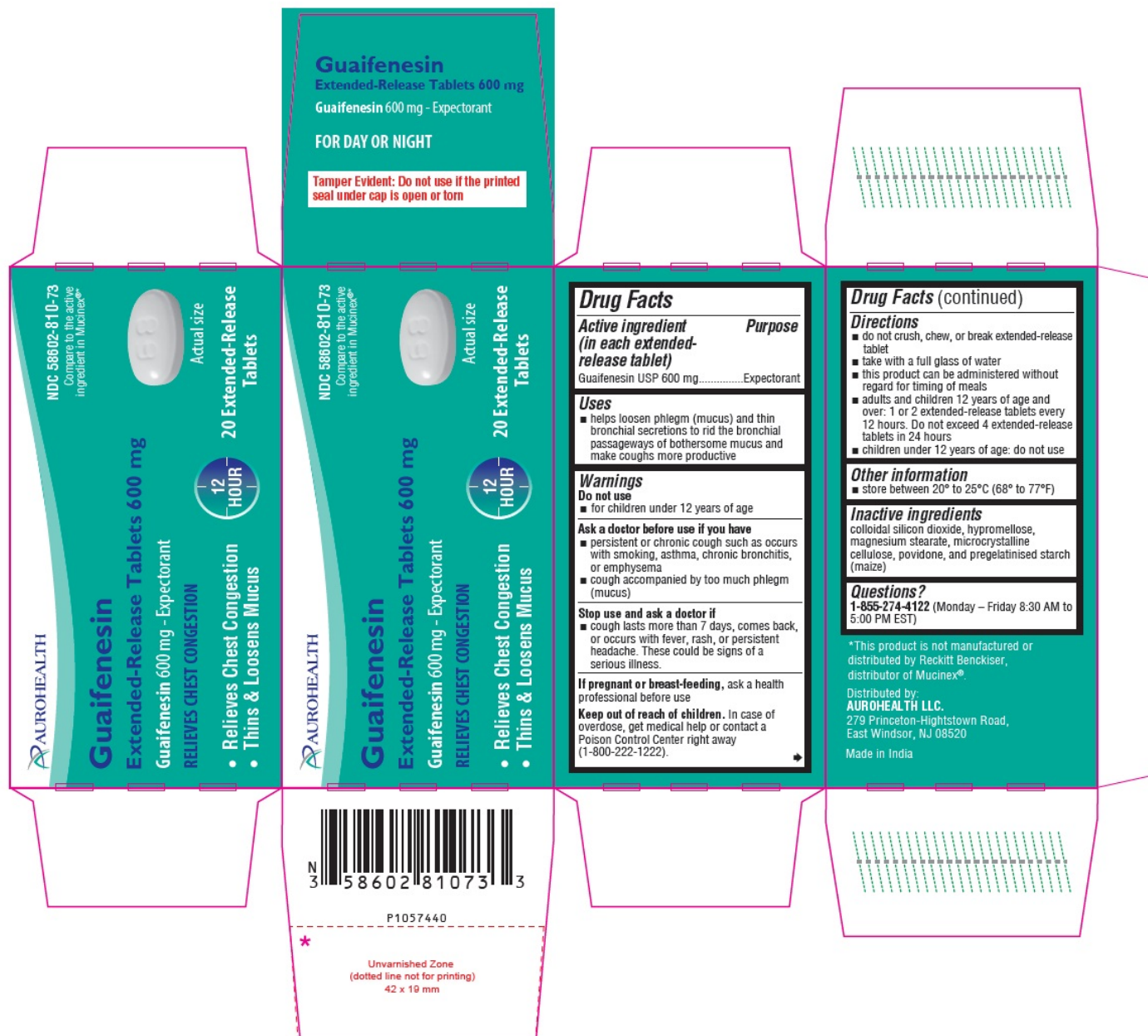
RELIEVES CHEST CONGESTION

- Relieves Chest Congestion
- Thins & Loosens Mucus

12
HOUR

Actual size

20 Extended-Release
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**

Guaifenesin 600 mg - Expectorant

RELIEVES CHEST CONGESTION

- Relieves Chest Congestion
- Thins & Loosens Mucus

Actual size

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: 10/2024

Aurohealth LLC