

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)

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 (20 Tablet Label)

AUROHEALTH

NDC 58602-811-05

MAXIMUM STRENGTH

**Guaifenesin
Extended-Release
Tablets 1200 mg**

EXPECTORANT

12
HOUR

- Relieves Chest Congestion
- Thins And Loosens Mucus

14
Extended-Release
Tablets

AUROHEALTH
NDC 58602-811-05
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Guaifenesin
Extended-Release
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EXPECTORANT
12 HOUR
• Relieves Chest Congestion
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14 Extended-Release Tablets

Tamper evident: Do not use if this printed seal under cap is open or torn

Purpose
Expectorant

Drug Facts
Active ingredient
(in each extended-release tablet)
Guaifenesin USP 1200 mg.....

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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).

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279 Princeton-Hightstown Road
East Windsor, NJ 08520 Code: APDRUGS/04/2016

P1428476

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

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 1200 mg (20 Tablet Carton Label)

AUROHEALTH

NDC 58602-811-05

Compare to the active
Ingredient in Maximum

Strength Mucinex®*

MAXIMUM STRENGTH

Guaifenesin Extended-Release Tablets 1200 mg
EXPECTORANT

- Relieves Chest Congestion
- Thins And Loosens Mucus

12
HOUR

14

Extended-Release Tablets



PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 1200 mg Blister Carton (14 (1 x 14) Tablets)

AUROHEALTH

NDC 58602-811-01

Compare to the active
 Ingredient in Maximum
 Strength Mucinex®*

MAXIMUM STRENGTH

**Guaifenesin
Extended-Release Tablets 1200 mg
EXPECTORANT**

- Relieves Chest Congestion
- Thins And Loosens Mucus

**14
Extended-Release
Tablets**

12 HOUR



GUAIFENESIN

guaifenesin tablet, extended release

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:58602-811

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:58602-811-05	1 in 1 CARTON	10/21/2019	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:58602-811-73	1 in 1 CARTON	10/21/2019	
2		20 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:58602-811-57	1 in 1 CARTON	10/21/2019	
3		28 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:58602-811-12	1 in 1 CARTON	10/21/2019	
4		40 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:58602-811-60	1 in 1 CARTON	10/21/2019	
5		42 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:58602-	100 in 1 BOTTLE; Type 0: Not a Combination	10/21/2019	

6	811-21	Product	10/21/2019	
7	NDC:58602-811-01	1 in 1 CARTON	10/21/2019	
7		14 in 1 BLISTER PACK; Type 0: Not a Combination Product		
8	NDC:58602-811-02	2 in 1 CARTON	10/21/2019	
8		14 in 1 BLISTER PACK; Type 0: Not a Combination Product		
9	NDC:58602-811-03	3 in 1 CARTON	10/21/2019	
9		14 in 1 BLISTER PACK; Type 0: Not a Combination Product		
10	NDC:58602-811-56	4 in 1 CARTON	01/31/2020	
10		14 in 1 BLISTER PACK; Type 0: Not a Combination Product		
11	NDC:58602-811-64	1 in 1 CARTON	11/26/2020	
11		7 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(58602-811) , MANUFACTURE(58602-811)

Revised: 11/2023

Aurohealth LLC