

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 Tablets Label)

Healthy Living™

NDC 58602-853-73

Guaifenesin

Extended-Release Tablets 600 mg

EXPECTORANT

12 HOUR

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

20 Extended-Release Tablets



Drug Facts	Purpose
Active ingredient (In each extended-release tablet)	Expectorant
Guaifenesin USP 600 mg	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 the printed seal under cap is open or torn	
Inactive ingredients colloidal silicon dioxide, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, and pregelatinized 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 2572 Brunswick Pike, Lawrenceville, NJ 08648 Made in India Code: AP/DRUGS/04/2016	

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

Healthy Living™

NDC 58602-853-73

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-Release
Tablets



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

Healthy Living™

**Guaifenesin
extended-release tablets 600 mg**

Expectorant

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

12 Hour

***Compare**

to the Active
Ingredient in
Mucinex®

100
Extended-Release
Tablets



GUAIFENESIN

guaifenesin tablet, extended release

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58602-853
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength

GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	600 mg
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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:58602-853-73	1 in 1 CARTON	08/13/2020	
1		20 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:58602-853-12	1 in 1 CARTON	08/13/2020	
2		40 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:58602-853-21	1 in 1 CARTON	08/13/2020	
3		100 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:58602-853-96	1 in 1 CARTON	08/13/2020	
4		20 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:58602-853-97	2 in 1 CARTON	08/13/2020	
5		20 in 1 BLISTER PACK; Type 0: Not a Combination Product		
6	NDC:58602-853-98	5 in 1 CARTON	11/01/2022	
6		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	08/13/2020	

Labeler - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650918514	ANALYSIS(58602-853) , MANUFACTURE(58602-853)

Revised: 12/2023

Aurohealth LLC