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

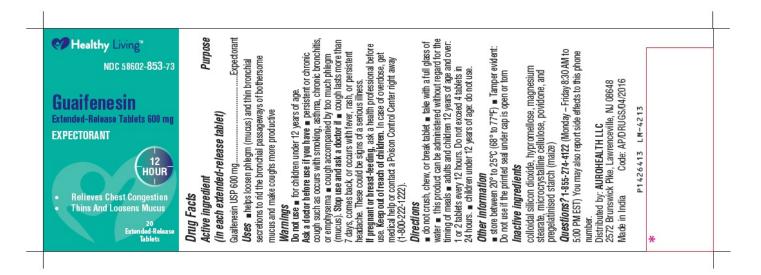
Guaifenesin Extended-Release Tablets 600 mg

EXPECTORANT

12 HOUR

- Relieves Chest Congestion
- Thins And Loosens Mucus

20 Extended-Release Tablets



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

Healthy Living[™]

NDC 58602-853-73

Compare to the active ingredient in Mucinex®*

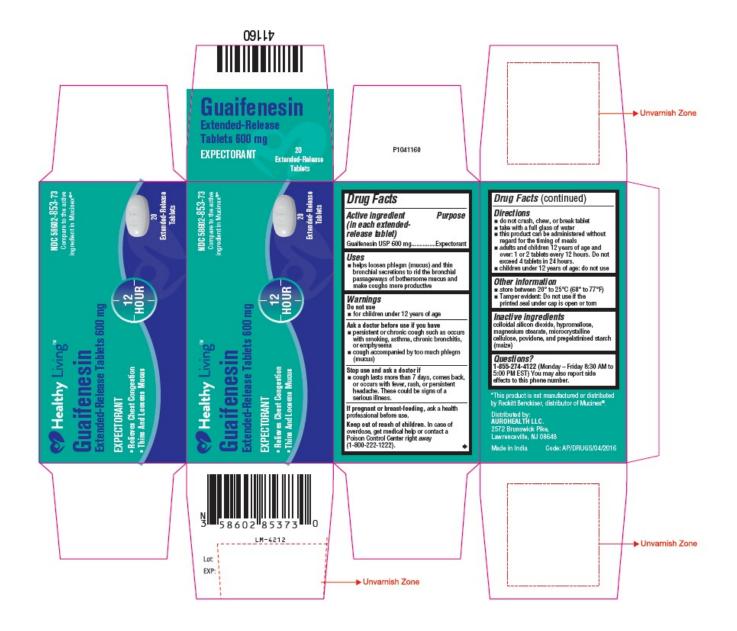
Guaifenesin Extended-release Tablets 600 mg

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

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