

**GUAIFENESIN - guaifenesin tablet, extended release  
WALGREEN CO.**

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***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: **WALGREEN CO.**  
**200 WILMOT RD., DEERFIELD, IL 60015**  
**100% SATISFACTION GUARANTEED**  
**walgreens.com**  
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**MADE IN INDIA**

Code: AP/DRUGS/04/2016

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

**NDC 0363-0033-01**

***Walgreens***

**Compare to the active ingredient  
in Mucinex<sup>®</sup> MaximumStrength<sup>††</sup>**

**WALGREENS  
PHARMACIST RECOMMENDED**

**12 HOUR  
Mucus  
Relief ER  
GUAIFENESIN EXTENDED-RELEASE  
TABLETS, 1200 mg / EXPECTORANT**

- Maximum Strength                      12 Hour**
- Relieves chest congestion
  - Thins & loosens mucus

**14  
EXTENDED-  
RELEASE  
TABLETS**

69  
**ACTUAL SIZE**



**GUAIFENESIN**  
guaifenesin tablet, extended release

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0363-0033
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	1200 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>HYPROMELLOSE 2208 (15000 MPA.S)</b> (UNII: Z78RG6M2N2)	
<b>HYPROMELLOSE 2910 (10000 MPA.S)</b> (UNII: 0HO1H52958)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE 101</b> (UNII: 7T9FYH5QMK)	
<b>MICROCRYSTALLINE CELLULOSE 102</b> (UNII: PNR0YF693Y)	
<b>POVIDONE K90</b> (UNII: RDH86HJV5Z)	
<b>POVIDONE K25</b> (UNII: K0KQV10C35)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	

## Product Characteristics

<b>Color</b>	WHITE (white to off-white)	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	21mm
<b>Flavor</b>		<b>Imprint Code</b>	L;69
<b>Contains</b>			

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:0363-0033-01	1 in 1 CARTON	05/08/2020	
1		14 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0363-0033-02	2 in 1 CARTON	05/08/2020	
2		14 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:0363-0033-03	3 in 1 CARTON	04/01/2021	
3		14 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	05/08/2020	

**Labeler** - WALGREEN CO. (008965063)

**Registrant** - Aurohealth LLC (078728447)

### Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650918514	ANALYSIS(0363-0033) , MANUFACTURE(0363-0033)

Revised: 12/2023

WALGREEN CO.