

**GUAIFENESIN- guaifenesin tablet, extended release**  
**BluePoint Laboratories**

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**Guaifenesin Extended Release Tablets 600 mg**

***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.

Manufactured by:

**APL Healthcare Limited Unit-IV.**

Tirupati (Dt) - 524421, India

For BluePoint Laboratories

Made in India

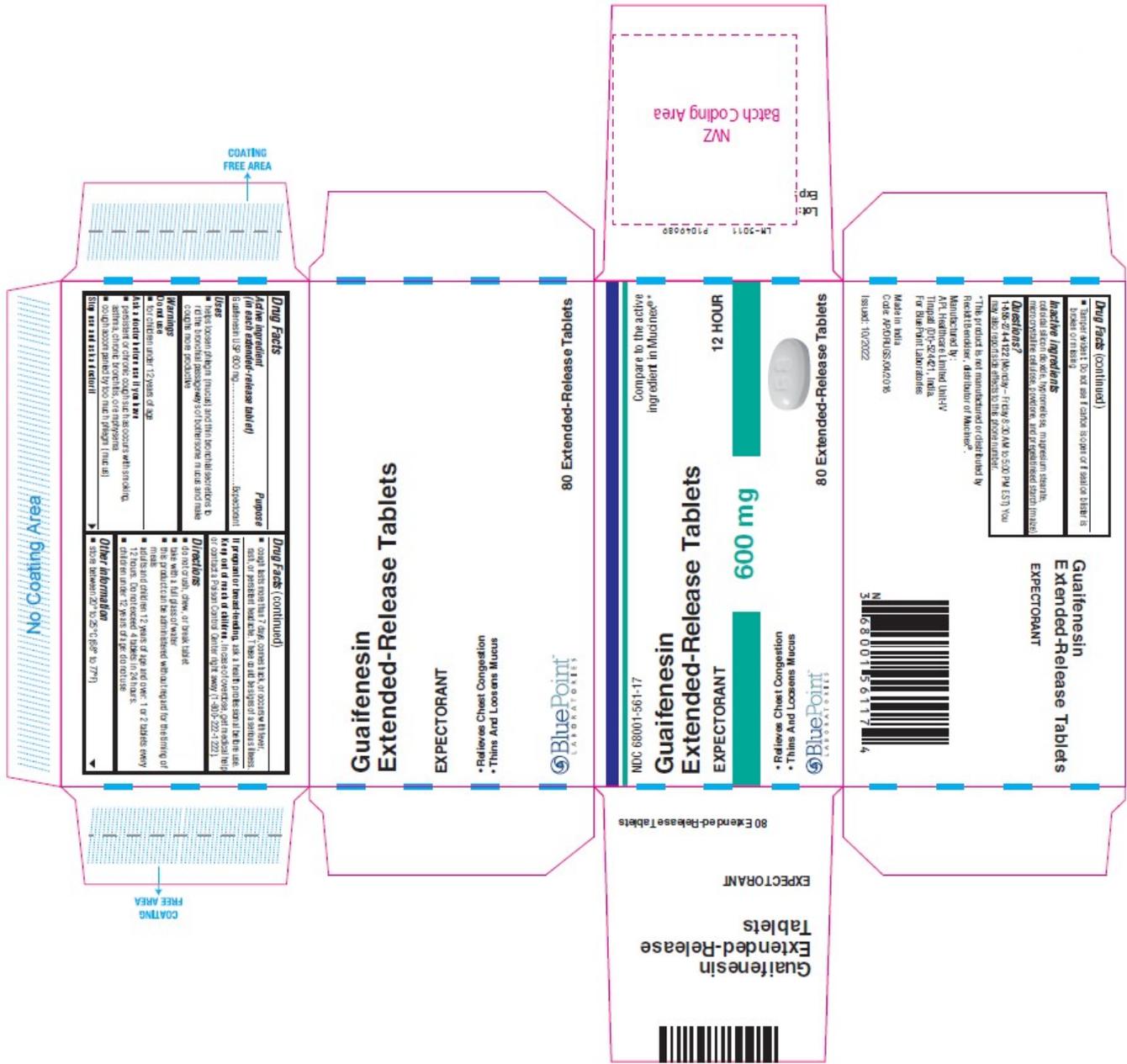
Code: AP/DRUGS/04/2016

Rev: 10/2022

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 600 mg Blister Foil and 600 mg Carton (80 Extended-Release Tablets, 1x10's).**

Blister Pack : NDC 68001-561-16





# GUAIFENESIN

guaifenesin tablet, extended release

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68001-561
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	600 mg

## Inactive Ingredients

Ingredient Name	Strength
<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>	16mm
<b>Flavor</b>		<b>Imprint Code</b>	L;68
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68001-561-17	8 in 1 CARTON	03/15/2023	
1	NDC:68001-561-16	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	03/15/2023	

**Labeler** - BluePoint Laboratories (985523874)

## Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650918514	analysis(68001-561) , manufacture(68001-561)

Revised: 12/2023

BluePoint Laboratories