

**GUAIFENESIN- guaifenesin tablet, extended release  
AMERISOURCE BERGEN**

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**Guaifenesin**

***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 extended-release 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: one or two extended-release tablets

every 12 hours. Do not exceed 4 extended-release tablets in 24 hours.

- children under 12 years of age: do not use

### **Other information**

- store between 20-25°C (68-77°F)
- **TAMPER EVIDENT: DO NOT USE IF CARTON IS OPEN OR IF PRINTED SEAL ON BLISTER IS BROKEN OR MISSING.**

### **Inactive ingredients**

colloidal silicon dioxide, FD&C blue #2 aluminum lake, hypromellose, magnesium stearate, povidone.

### **Questions?**

call toll-free Monday to Friday 8:30 am to 5:00 pm EST at **1-800-406-7984**.

Distributed By:

AmerisourceBergen

1 West First Avenue

Conshohocken, PA 19428

PRODUCT OF INDIA

CODE No.: PB/DRUGS/1809-OSP

0425

### **PRINCIPAL DISPLAY PANEL - 600 mg Tablet Blister Pack Carton**

NDC 46122-750-51

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

GOOD  
NEIGHBOR  
PHARMACY<sup>®</sup>

12 HOUR

Mucus • ER  
Guaifenesin Extended-Release  
Tablets, 600 mg

Expectorant

- Relieves Chest Congestion
- Thins and Loosens Mucus

20 Extended-Release Tablets



## GUAIFENESIN

guaifenesin tablet, extended release

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:46122-750
<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>FD&amp;C BLUE NO. 2</b> (UNII: L06K8R7DQK)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6130)	

**POVIDONE, UNSPECIFIED** (UNII: FZ989GH94E)

### Product Characteristics

<b>Color</b>	white (blue/white mottled)	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	16mm
<b>Flavor</b>		<b>Imprint Code</b>	RH98
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46122-750-51	2 in 1 CARTON	08/11/2023	
1		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	ANDA209254	08/11/2023	

**Labeler** - AMERISOURCE BERGEN (007914906)

### Establishment

Name	Address	ID/FEI	Business Operations
Sun Pharmaceutical Industries Limited		650456002	manufacture(46122-750)

Revised: 4/2025

AMERISOURCE BERGEN