

**GUAIFENESIN 600 MG- guaifenesin tablet, extended release**  
**GUAIFENESIN 1200 MG- guaifenesin tablet, extended release**  
**Dr. Reddy's Laboratories Inc.**

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**Drug Facts**

**Active ingredient(s)**

Guaifenesin 600 mg (for 600mg)

Guaifenesin 1200 mg (for 1200 mg)

**Purpose**

Expectorant

**Use(s)**

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

**Warnings**

Applicable warning(s) in 201.66(c)(5)(i) and (ii)

**Do not use**

- For children under 12 years age

**Ask a doctor before use if**

- 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 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 Pregnancy/Breastfeeding,**

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 extended-release tablets every 12 hours. Do not exceed 4 extended-release tablets in 24 hours (for 600 mg)
- adults and children 12 years of age and over: 1 extended-release tablet every 12 hours. Do not exceed 2 extended-release tablets in 24 hours (for 1200 mg)
- children under 12 years of age: do not use

### **Other information**

- store at 20-25°C (68-77°F)

### **Inactive ingredients**

carbomer homopolymer type B, colloidal silicon dioxide, ferric oxide red, hydroxypropyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, sodium starch glycolate type A

### **Questions?**

call **1-888-375-3784** Weekdays (9am - 8pm EST)

You may also report side effects to this phone number.

Distributed by:

**Dr. Reddy's Laboratories, Inc.**

Princeton, NJ 08540

**Made in India**

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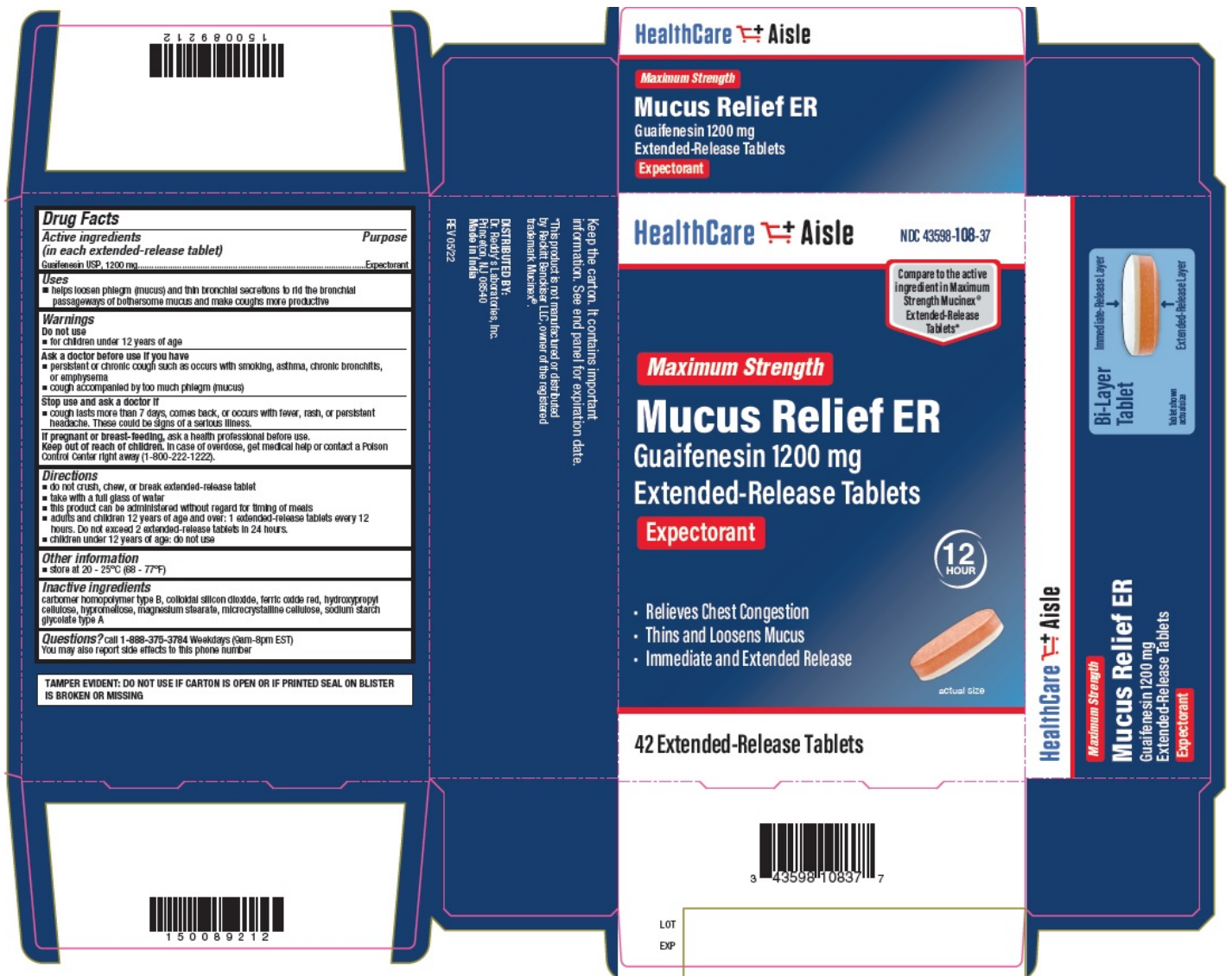
**Principal Display Panel- 600mg Carton**

**Guaifenesin Extended-Release Tablets 600 mg** Carton Label



**Principal Display Panel - 1200 mg Carton**

**Guaifenesin Extended-Release Tablets 1200 mg Carton Label**



## GUAIFENESIN 600 MG

guaifenesin tablet, extended release

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:43598-110(NDC:43598-008)
<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>Carbomer Homopolymer Type B (Allyl Pentaerythritol Crosslinked)</b> (UNII: HHT01Z NK31)	
<b>Silicon Dioxide</b> (UNII: ETJ7Z 6XBU4)	
<b>Ferric Oxide Red</b> (UNII: 1K09F3G675)	

<b>Hydroxypropyl Cellulose (110000 Wamw)</b> (UNII: 5Y0974F5PW)	
<b>Hypromellose 2910 (10000 Mpa.S)</b> (UNII: 0HO1H52958)	
<b>Hypromellose 2208 (4000 Mpa.S)</b> (UNII: 39J80LT57T)	
<b>Magnesium Stearate</b> (UNII: 70097M6I30)	
<b>Microcrystalline Cellulose</b> (UNII: OP1R32D61U)	
<b>Sodium Starch Glycolate Type A Potato</b> (UNII: 5856J3G2A2)	

### Product Characteristics

<b>Color</b>	PINK (White on debossed side and Light Pink to Pink on other side )	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	16mm
<b>Flavor</b>		<b>Imprint Code</b>	6
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43598-110-01	5 in 1 CARTON	09/01/2022	
1		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	ANDA215932	09/01/2022	

## GUAIFENESIN 1200 MG

guaifenesin tablet, extended release

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:43598-108(NDC:43598-009)
<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	1200 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>Carbomer Homopolymer Type B (Allyl Pentaerythritol Crosslinked)</b> (UNII: HHT01Z NK31)	
<b>Silicon Dioxide</b> (UNII: ETJ7Z 6XBU4)	

<b>Ferric Oxide Red</b> (UNII: 1K09F3G675)	
<b>Hydroxypropyl Cellulose (110000 Wamw)</b> (UNII: 5Y0974F5PW)	
<b>Hypromellose 2910 (10000 Mpa.S)</b> (UNII: 0HO1H52958)	
<b>Hypromellose 2208 (4000 Mpa.S)</b> (UNII: 39J80LT57T)	
<b>Magnesium Stearate</b> (UNII: 70097M6I30)	
<b>Microcrystalline Cellulose</b> (UNII: OP1R32D61U)	
<b>Sodium Starch Glycolate Type A Potato</b> (UNII: 5856J3G2A2)	

### Product Characteristics

<b>Color</b>	PINK (White on debossed side and Light Pink to Pink on other side )	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	22mm
<b>Flavor</b>		<b>Imprint Code</b>	12
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43598-108-37	3 in 1 CARTON	09/01/2022	
1		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	ANDA215932	09/01/2022	

**Labeler** - Dr. Reddy's Laboratories Inc. (802315887)

Revised: 6/2022

Dr. Reddy's Laboratories Inc.