

**GUAIFENESIN- guaifenesin tablet, extended release  
Granules India Ltd**

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**Guaifenesin Extended-Release Tablets, 600 mg and 1200 mg**

***Active ingredients (in each extended-release tablet)***

Guaifenesin 600 mg (for 600 mg)

Guaifenesin 1200 mg (for 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 extended-release tablet
- take with a full glass of water
- this product can be administered without regard for 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***

- **Tamper evident: Do not use if carton is open or if printed seal on blister is broken or missing.**
- store between 20-25°C (68-77°F)

### ***Inactive ingredients***

carbomer homopolymer type B; hypromellose; magnesium stearate; microcrystalline cellulose; sodium starch glycolate

### ***Questions?***

Contact 1-877-770-3183

Mon-Fri 8:00 AM EST to 5:00 PM PST.

### **PRINCIPAL DISPLAY PANEL - 600 mg Blister Carton Label**

NDC 62207- 839-72 **Compare to the active ingredient of Mucinex<sup>®</sup>**

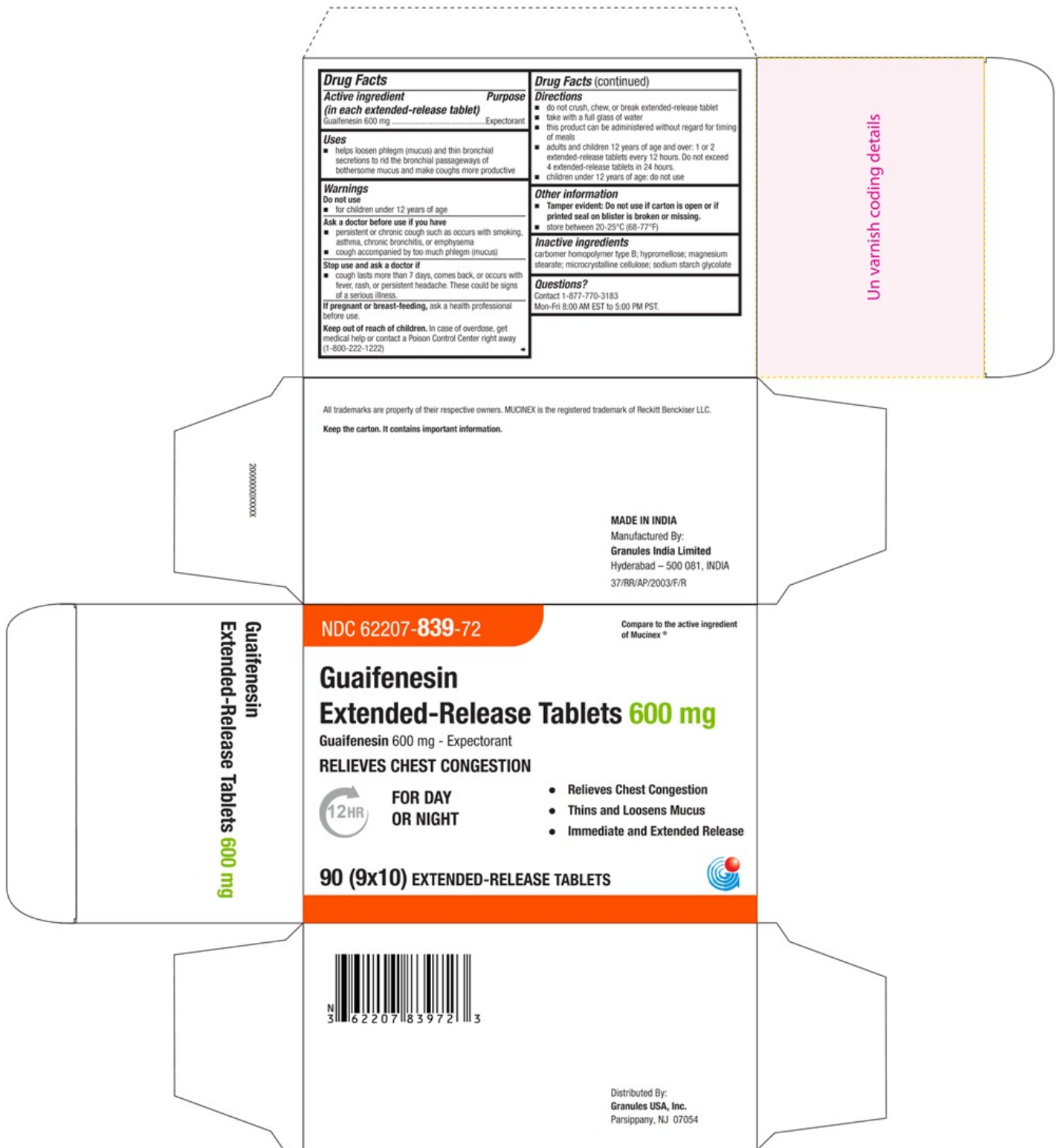
**Guaifenesin  
Extended-Release Tablets 600 mg**

**Guaifenesin** 600 mg - Expectorant

**RELIEVES CHEST CONGESTION**

**12HR FOR DAY • Relieves Chest Congestion  
OR NIGHT • Thins and Loosens Mucus  
• Immediate and Extended Release**

**90 (9 x 10) EXTENDED-RELEASE TABLETS**



## PRINCIPAL DISPLAY PANEL - 1200 mg Blister Carton Label

NDC 62207- 840-71 Compare to the active ingredient of Mucinex®

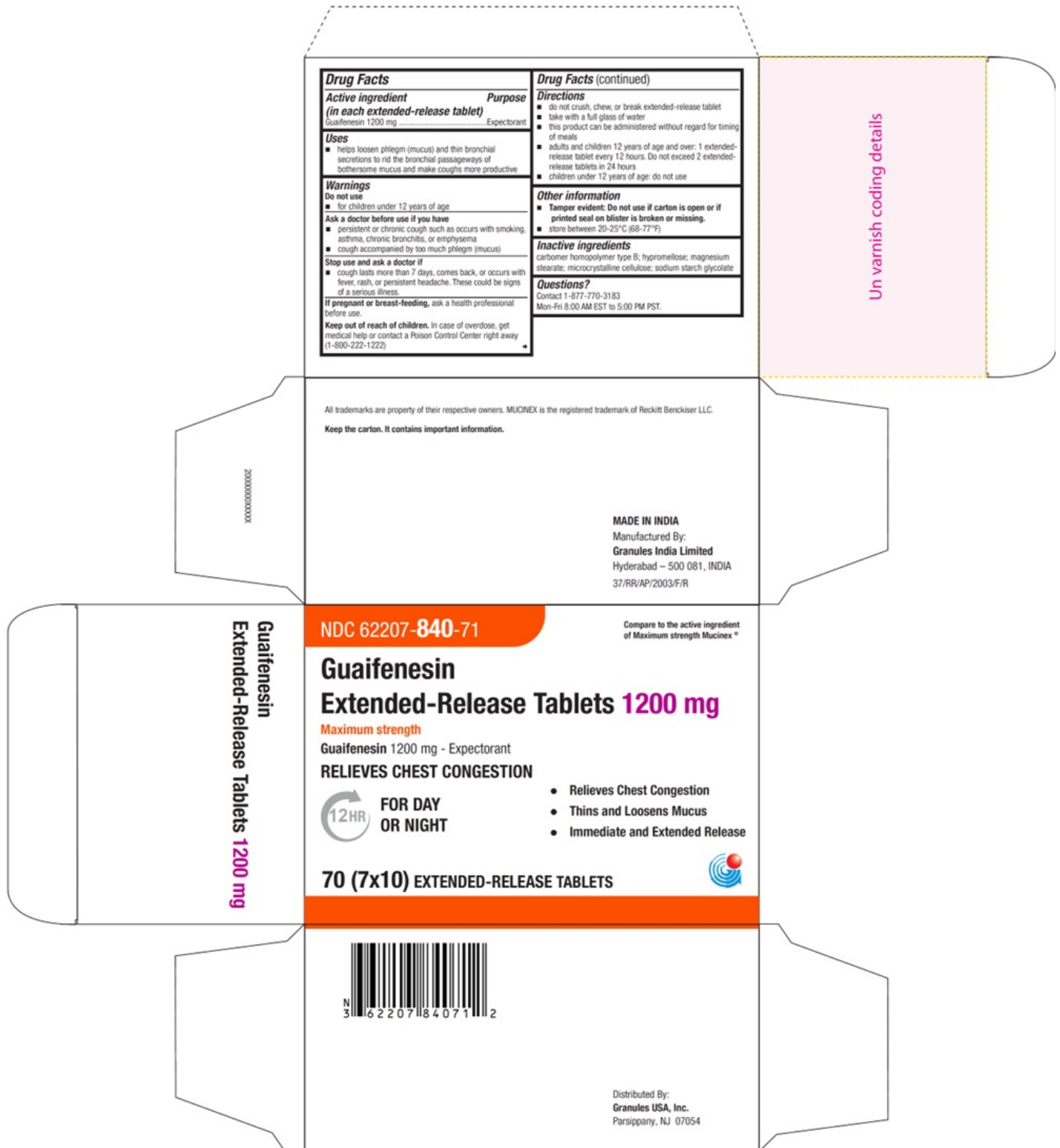
**Guaifenesin**  
**Extended-Release Tablets 1200 mg**  
**Maximum strength**

# Guaifenesin 1200 mg - Expectorant

## RELIEVES CHEST CONGESTION

**12HR FOR DAY • Relieves Chest Congestion  
OR NIGHT • Thins and Loosens Mucus  
• Immediate and Extended Release**

**70 (7 x 10) EXTENDED-RELEASE TABLETS**



# PRINCIPAL DISPLAY PANEL

Manufactured by:  
Granules India Limited  
Sy No. 160/A, 161/E, 162 & 174/A, Gagillapur Village, Dundigal – Gandimaisamma Mandal,  
Medchal – Malkajgiri District – 500 043, India

## Guaifenesin Extended-Release Tablets 1200 mg

Pack Size: 300 x 14 tablets

Store between 20° to 25°C (68° to 77°F)

M.L.No.: 37/RR/AP/2003/F/R

Perrigo Part No.: 4A65KAA

NDC: 62207-840-99

EXP: MM/YYYY      LOT: XXXXXXXX      QTY: 0300



(01)50362207840991(17)YMMDD(10)XXXXXXXX



(00)189038320000000011

FG Code: 7000000XXXX  
Case No.: 0000

Manufactured by:  
Granules India Limited  
Sy No. 160/A, 161/E, 162 & 174/A, Gagillapur Village, Dundigal – Gandimaisamma Mandal,  
Medchal – Malkajgiri District – 500 043, India

## Guaifenesin Extended-Release Tablets 1200 mg

Pack Size: 300 x 14 tablets

Store between 20° to 25°C (68° to 77°F)

M.L.No.: 37/RR/AP/2003/F/R

Perrigo Part No.: 4A65KAA

NDC: 62207-840-99

EXP: MM/YYYY      LOT: XXXXXXXX      QTY: 0300



(01)50362207840991(17)YMMDD(10)XXXXXXXX



(00)189038320000000011

FG Code: 7000000XXXX  
Case No.: 0000

# Guaifenesin Extended-Release Tablets 1200 mg

Each Extended release tablet contains

Guaifenesin, USP 1200mg

Batch No. : XXXXXXXX

Mfg.Dt. : YYYY/MM

Exp.Dt. : YYYY/MM

Mfg. Lic. No. : 37/RR/AP/2003/F/R

NDC No. : 62207-840-93

Perrigo product number: 65KAA

Perrigo PO:

Storage : Store between 20°C to 25°C (68°F to 77°F)

Caution: For repacking only.



(01)50362207840939(17)000000(10)XXXXXXXX

Ship From:

Granules India Limited  
Sy.No. 160/A, 161/E, 162 & 174/A,  
Gagillapur Village, Dundigal-Gandimaisamma Mandal,  
Medchal-Malkajgiri District – 500043, Telangana, INDIA

No. of Units : 5x2000 no's

Gross Wt. : 00.000 Kg

Tare Wt. : 00.000 Kg

Net Wt. : 00.000 Kg

Box No. : 000

Country of Origin: INDIA

FG Code : 70000002884



(00)189038320000000004

Ship To:

Perrigo Company Plt 7  
506 Eastern Ave  
Allegan, MI 49010

## GUAIFENESIN

guaifenesin tablet, extended release

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62207-839
Route of Administration	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 SUCROSE CROSSLINKED)</b> (UNII: Z135WT9208)			
<b>HYPROMELLOSE 2910 (5 MPA.S)</b> (UNII: R75537T0T4)			
<b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2)			
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)			
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)			
<b>HYPROMELLOSE 2910 (10000 MPA.S)</b> (UNII: 0HO1H52958)			

Product Characteristics			
<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	16mm
<b>Flavor</b>		<b>Imprint Code</b>	G;600
<b>Contains</b>			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62207-839-72	9 in 1 CARTON	12/18/2020	
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	ANDA213420	12/18/2020	

## GUAIFENESIN

guaifenesin tablet, extended release

Product Information			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:62207-840
<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>HYPROMELLOSE 2910 (10000 MPA.S)</b> (UNII: 0HO1H52958)	
<b>CARBOMER HOMOPOLYMER TYPE B (ALLYL SUCROSE CROSSLINKED)</b> (UNII: Z135WT9208)	
<b>HYPROMELLOSE 2910 (5 MPA.S)</b> (UNII: R75537T0T4)	
<b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	OVAL (Elliptical)	<b>Size</b>	22mm
<b>Flavor</b>		<b>Imprint Code</b>	G;1200
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62207-840-71	7 in 1 CARTON	12/18/2020	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:62207-840-99	4200 in 1 BAG; Type 0: Not a Combination Product	12/18/2020	
3	NDC:62207-840-93	10000 in 1 BOX; Type 0: Not a Combination Product	10/31/2022	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA213420	12/18/2020	

**Labeler** - Granules India Ltd (915000087)

## Establishment

Name	Address	ID/FEI	Business Operations
Ganules India Limited		918609236	analysis(62207-839, 62207-840) , label(62207-839, 62207-840) , manufacture(62207-839, 62207-840) , pack(62207-839, 62207-840)

Revised: 9/2024

Granules India Ltd