

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

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[®]**

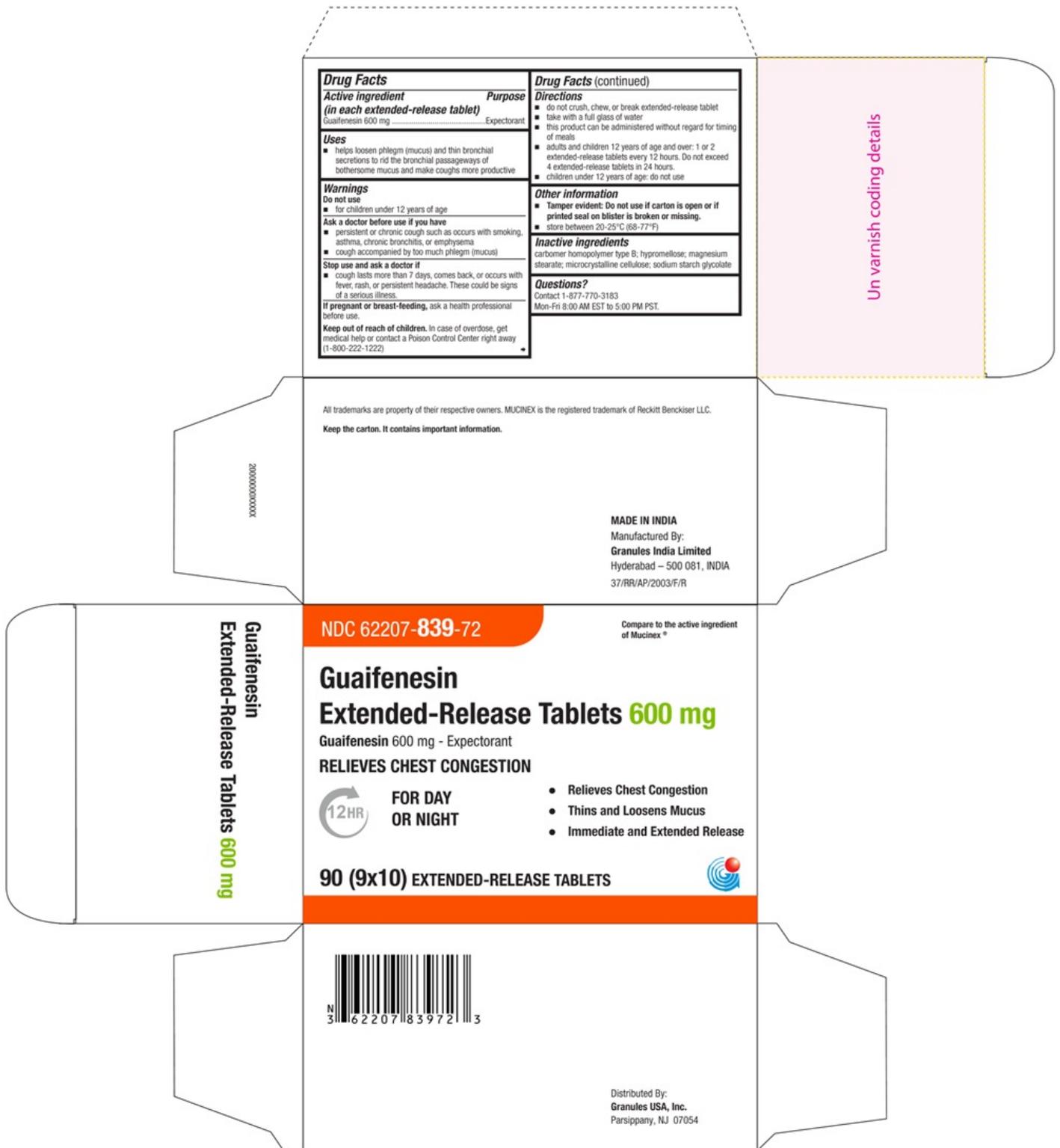
**Guaifenesin
Extended-Release Tablets 600 mg**

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**

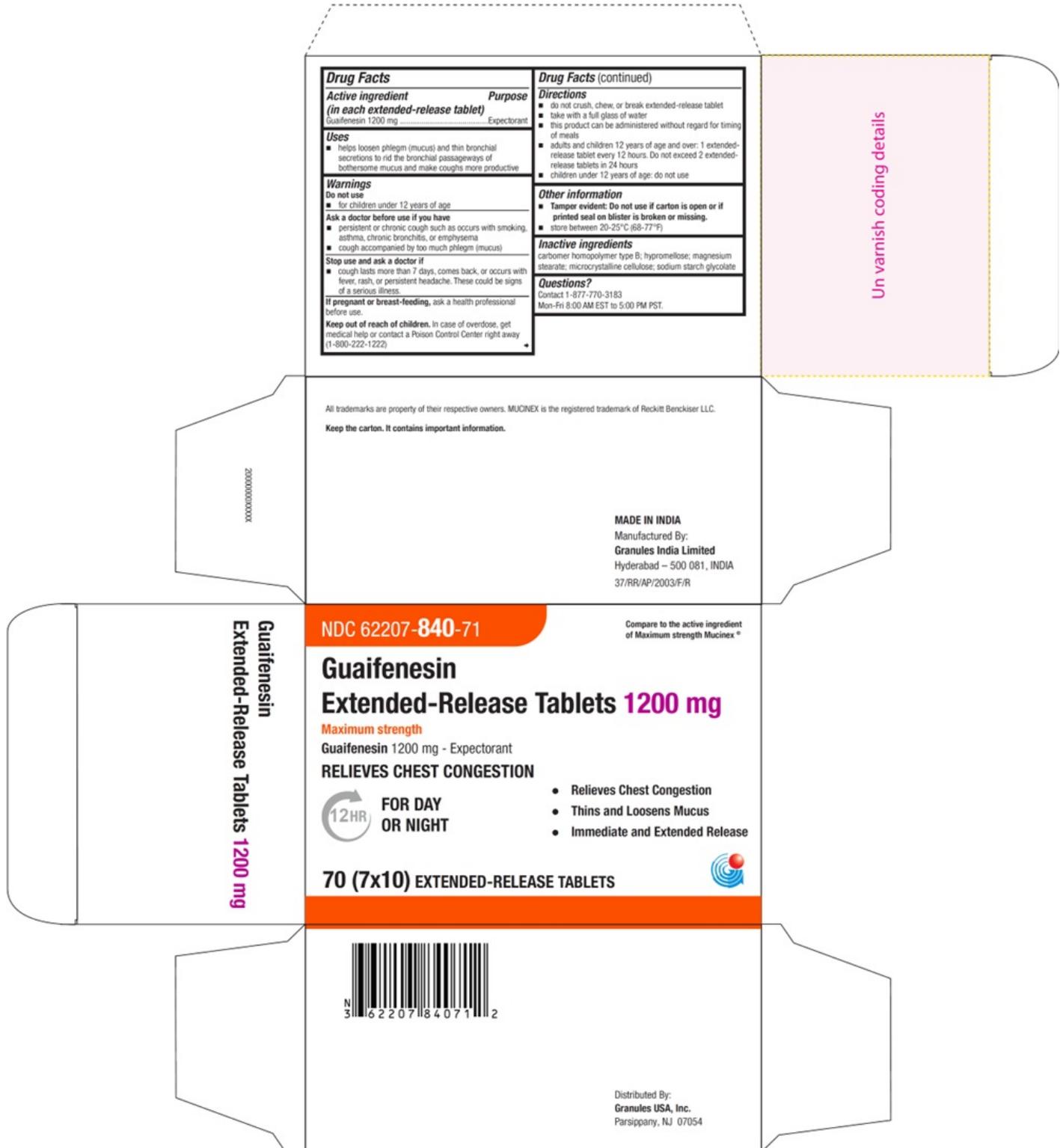
Maximum strength

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: 7000000XXXXX
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: 7000000XXXXX
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)1890383200000000004

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	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)		GUAIFENESIN	600 mg	
Inactive Ingredients				
Ingredient Name			Strength	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)				
CARBOMER HOMOPOLYMER TYPE B (ALLYL SUCROSE CROSSLINKED) (UNII: Z135WT9208)				
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
HYPROMELLOSE 2910 (10000 MPA.S) (UNII: 0HO1H52958)				
Product Characteristics				
Color	white	Score	no score	
Shape	OVAL	Size	16mm	
Flavor		Imprint Code	G;600	
Contains				
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			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62207-840
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)		GUAIFENESIN	1200 mg

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSE 2910 (10000 MPA.S) (UNII: 0HO1H52958)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL SUCROSE CROSSLINKED) (UNII: Z135WT9208)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

Product Characteristics

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

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: 12/2025

Granules India Ltd