

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

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 (8am - 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

I 0721

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

2 2 2 1 0 1 0 5 1



Drug Facts

Active ingredient (in each extended-release tablet) **Purpose**
Guaifenesin USP, 1200 mg 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 extended-release tablet every 12 hours. Do not exceed 2 extended-release tablets in 24 hours.
- 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

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPEN OR IF PRINTED SEAL ON BLISTER IS BROKEN OR MISSING.

Keep the carton. It contains important information. See end panel for expiration date.

*This product is not manufactured or distributed by HealthCare Aisle, Inc., owner of the registered trademark Mucosin®.

DISTRIBUTED BY:
Dr. Reddy's Laboratories, Inc.
Parsippany, NJ 08859
Made in India
REF 02/25



HealthCare Aisle

Maximum Strength

Mucus Relief ER
Guaifenesin 1200 mg
Extended-Release Tablets
RELIEVES CHEST CONGESTION

HealthCare Aisle NDC: 43598-108-37

Compare to the active ingredient in Maximum Strength Mucosin® Extended-Release Tablets*

Maximum Strength

Mucus Relief ER
Guaifenesin 1200 mg
Extended-Release Tablets
Expectorant

RELIEVES CHEST CONGESTION **12 HOUR**

- Thins & Loosens Mucus
- Immediate & Extended Release



actual size

42 Extended-Release Tablets

3 43598 10837 7

LOT: _____
EXP: _____

FOR DAY OR NIGHT

HealthCare Aisle

Maximum Strength

Mucus Relief ER
Guaifenesin 1200 mg
Extended-Release Tablets
RELIEVES CHEST CONGESTION

GUAIFENESIN 600 MG

guaifenesin tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43598-110(NDC:43598-008)
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
Carbomer Homopolymer Type B (Allyl Pentaerythritol Crosslinked) (UNII: HHT01ZNK31)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Ferric Oxide Red (UNII: 1K09F3G675)	

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

Product Characteristics

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

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

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43598-108(NDC:43598-009)
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
Carbomer Homopolymer Type B (Allyl Pentaerythritol Crosslinked) (UNII: HHT01ZNK31)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Ferric Oxide Red (UNII: 1K09F3G675)	

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

Product Characteristics

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

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: 9/2025

Dr. Reddy's Laboratories Inc.