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 phlegum (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 aPoison 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: 1or 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

I 07/2022

Principal Display Panel

OTC Medicine

Guaifenesin Extended-Release Tablets 600 mg Carton Label

OTC Medicine

Guaifenesin Extended-Release Tablets 1200 mg Carton Label

GUAIFENESIN 600 MG

guaifenesin tablet, extended release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	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:43598-008-40	2 in 1 CARTON	03/15/2022	
1	NDC:43598-008-20	20 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:43598-008-01	5 in 1 CARTON	09/01/2022	
2	NDC:43598-008-20	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	03/15/2022	

GUAIFENESIN 1200 MG

guaifenesin tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	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:43598-009-25	2 in 1 CARTON	03/15/2022	
1	NDC:43598-009-74	14 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:43598-009-37	3 in 1 CARTON	09/01/2022	
2	NDC:43598-009-74	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	03/15/2022	

Labeler - Dr. Reddy’s Laboratories Inc. (802315887)

Establishment

Name	Address	ID/FEI	Business Operations
Dr. Reddy's Laboratories Limited FTO3		918608162	analysis(43598-008, 43598-009) , manufacture(43598-008, 43598-009)