GUAIFENESIN AND DEXTROMETHORPHAN HBR- guaifenesin and dextromethorphan hbr tablet, extended release
Dr. Reddy's Laboratories Inc.

Drug Facts

Active ingredients

(in each extended-release tablet)

Guaifenesin USP, 600 mg

Dextromethorphan Hydrobromide USP, 30 mg

Guaifenesin USP, 1200 mg

Dextromethorphan Hydrobromide USP, 60 mg

Purposes

Expectorant

Cough suppressant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily relieves:
  - cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants
  - the intensity of coughing
  - the impulse to cough to help you get to sleep

Warnings

Do not use

- for children under 12 years of age
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson’s disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

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)

When using this product

- do not use more than directed

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 tablet
- take with a full glass of water
- this product can be administered without regard for timing of meals
- children under 12 years of age: do not use

For 600 mg/30 mg:
- adults and children 12 years and older: 1 or 2 tablets every 12 hours; not more than 4 tablets in 24 hours.

For 1200 mg/60 mg:
- adults and children 12 years and older: 1 tablet every 12 hours; not more than 2 tablets in 24 hours.

Other information
- store at 20°C to 25°C (68°F to 77°F)

Inactive ingredients

carbomer homopolymer type B, colloidal silicon dioxide, FD & C Blue #1, ferric oxide yellow, hypromellose, magnesium stearate, microcrystalline cellulose and sodium starch glycolate.

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.

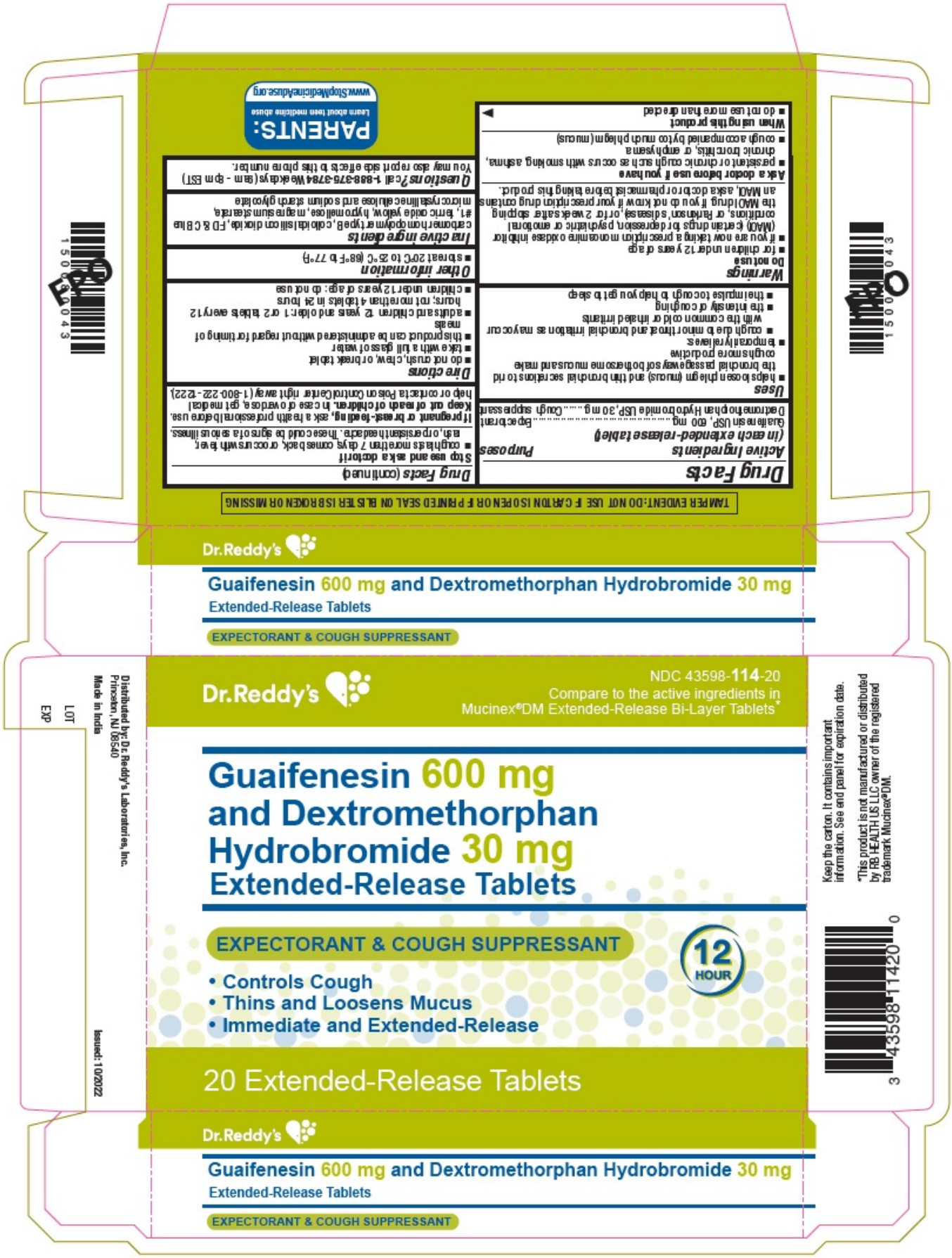
Princeton, NJ 08540

Made in India

Issued: 10/2022

Guaifenesin 600 mg and Dextromethorphan 30 mg Extended-Release Tablets

Carton:



Guaifenesin 1200 mg and Dextromethorphan 60 mg Extended-Release

Tablets

Carton:

GUAIFENESIN AND DEXTROMETHORPHAN HBR

guaifenesin and dextromethorphan hbr tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:43598-114
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	600 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
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 (UNII: H8AV0SQX4D)	

Product Characteristics

Color	WHITE (white to off white) , GREEN (light green to green)	**Score**	no score
Shape	OVAL	**Size**	16mm
Flavor		**Imprint Code**	3
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43598-114-20	1 in 1 CARTON	08/15/2023	
1		20 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:43598-114-40	2 in 1 CARTON	08/15/2023	
2		20 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:43598-114-01	5 in 1 CARTON	08/15/2023	

3		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	ANDA217340	08/15/2023	

GUAIFENESIN AND DEXTROMETHORPHAN HBR

guaifenesin and dextromethorphan hbr tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:43598-115
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	1200 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	60 mg

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
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 (UNII: H8AV0SQX4D)	

Product Characteristics

Color	WHITE (white to off white) , GREEN (light green to green)	**Score**	no score
Shape	OVAL	**Size**	22mm
Flavor		**Imprint Code**	6
Contains			

Packaging

			Marketing Start	Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43598-115-70	1 in 1 CARTON	08/15/2023	
1		7 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:43598-115-32	2 in 1 CARTON	08/15/2023	
2		7 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:43598-115-28	4 in 1 CARTON	08/15/2023	
3		7 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:43598-115-42	6 in 1 CARTON	08/15/2023	
4		7 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:43598-115-37	3 in 1 CARTON	08/15/2023	
5	NDC:43598-115-74	14 in 1 BLISTER PACK; Type 0: Not a Combination Product		
6	NDC:43598-115-56	4 in 1 CARTON	05/30/2024	
6	NDC:43598-115-74	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	ANDA217340	08/15/2023	

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

Establishment

Name	Address	ID/FEI	Business Operations
Dr. Reddy's Laboratories Limited-FTO3		918608162	manufacture(43598-114, 43598-115) , analysis(43598-114, 43598-115)

Revised: 3/2024 Dr. Reddy's Laboratories Inc.