

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

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**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.**





## GUAIFENESIN AND DEXTROMETHORPHAN HBR

guaifenesin and dextromethorphan hbr tablet, extended release

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:43598-231
<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	600 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3R0TS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg

### Inactive Ingredients

Ingredient Name	Strength
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<b>CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: HHT01ZNK31)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>HYPROMELLOSE 2910 (10000 MPA.S)</b> (UNII: 0HO1H52958)	
<b>HYPROMELLOSE 2208 (4000 MPA.S)</b> (UNII: 39J80LT57T)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>SODIUM STARCH GLYCOLATE TYPE A</b> (UNII: H8AV0SQX4D)	

### Product Characteristics

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43598-231-01	5 in 1 CARTON	11/23/2023	
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	ANDA217340	08/15/2023	

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guaifenesin and dextromethorphan hbr tablet, extended release

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:43598-232
<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
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	60 mg

Inactive Ingredients	
Ingredient Name	Strength
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<b>SODIUM STARCH GLYCOLATE TYPE A</b> (UNII: H8AV0SQX4D)	

Product Characteristics			
<b>Color</b>	WHITE (white to off white) , GREEN (light green to green)	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	22mm
<b>Flavor</b>		<b>Imprint Code</b>	6
<b>Contains</b>			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43598-232-37	3 in 1 CARTON	12/01/2023	
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	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(43598-231, 43598-232) , analysis(43598-231, 43598-232)

Revised: 12/2023

Dr. Reddy's Laboratories Inc.