

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:

Tablets

Carton:



MAXIMUM STRENGTH

Guaifenesin 1200 mg and Dextromethorphan Hydrobromide 60 mg

Extended-Release Tablets

EXPECTORANT & COUGH SUPPRESSANT

NDC 43598-115-70

Compare to the active ingredients in Maximum Strength Mucinex®DM Extended-Release Bi-Layer Tablets*

MAXIMUM STRENGTH

Guaifenesin 1200 mg and Dextromethorphan Hydrobromide 60 mg

Extended-Release Tablets

EXPECTORANT & COUGH SUPPRESSANT

12

HOUR

- Controls Cough
- Thins and Loosens Mucus
- Immediate and Extended-Release

7 Extended-Release Tablets



MAXIMUM STRENGTH

Guaifenesin 1200 mg and Dextromethorphan Hydrobromide 60 mg

Extended-Release Tablets

EXPECTORANT & COUGH SUPPRESSANT

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

*This product is not manufactured or distributed by RB-HEALTH US, LLC owner of the registered trademark Mucinex®DM.

LOT

EXP

Distributed by: Dr. Reddy's Laboratories, Inc.
Princeton, NJ 08540
Made in India

Issued: 10/2022



3 43598 11570 2

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

Drug Facts (continued)

Active Ingredients
(in each extended-release tablet)
Guaifenesin USP, 1200 mg
Dextromethorphan Hydrobromide USP, 60 mg
Cough suppressant

Purposes
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.

Uses
Helps to ease phlegm (mucus) and thin bronchial secretions to rid the bronchial passageway of bothersome mucus and make coughing more productive
to temporarily relieve cough due to minor throat and bronchial irritation as may occur with the common cold or irritated irritants
the intensity of coughing
their impulse to cough to help you get to sleep

Warnings
Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) for 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 chronic bronchitis, or emphysema, or persistent or chronic cough such as occurs with smoking, asthma, or cough accompanied by too much phlegm (mucus).
When using this product do not use more than directed

Drug Facts

Directions
Take with a full glass of water
do not crush, chew, or break tablet
this product can be administered without regard for timing of meals
adults and children 12 years and older: 1 tablet every 12 hours; not more than 2 tablets in 24 hours
children under 12 years of age: do not use

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

Keep out of reach of children. In case of overdose, get medical help or contact Poison Control Center right away (1-800-222-1222).

Warnings
If pregnant or breast-feeding, ask a health professional before use. Ask your health care provider if you are taking any other medicines.

Directions
Take with a full glass of water
do not crush, chew, or break tablet
this product can be administered without regard for timing of meals
adults and children 12 years and older: 1 tablet every 12 hours; not more than 2 tablets in 24 hours
children under 12 years of age: do not use

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

Keep out of reach of children. In case of overdose, get medical help or contact Poison Control Center right away (1-800-222-1222).

Warnings
If pregnant or breast-feeding, ask a health professional before use. Ask your health care provider if you are taking any other medicines.

PARENTS: Learn about teen medicine abuse
www.StopMedicineAbuse.org

Questions? Call 1-888-375-3784 weekdays (9am - 9pm EST)
You may also report side effects to this phone number.



1500630043



1500630043

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: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01Z NK31)	
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		
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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: HHT01Z NK31)	
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
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#	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.