

GUAIFENESIN AND DEXTROMETHORPHAN HBR- guaifenesin and dextromethorphan hbr tablet, extended release
Kroger Company

Guaifenesin and Dextromethorphan HBr

Drug Facts

<i>Active ingredients (in each extended-release tablet)</i>	<i>Purposes</i>
Dextromethorphan HBr 30 mg	Cough suppressant
Guaifenesin 600 mg	Expectorant

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 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 and older: 1 or 2 extended-release tablets every 12 hours; not more than 4 extended-release tablets in 24 hours
- children under 12 years of age: do not use

Other information

- Store between 20-25°C (68-77°F)

Inactive ingredients

carbomer homopolymer, colloidal silicon dioxide, hypromellose, magnesium stearate, maltodextrin, microcrystalline cellulose, povidone (K-30), stearic acid

Questions or comments?

1-800-632-6900

You may also report side effects to this phone number.

**DISTRIBUTED BY THE KROGER CO.
CINCINNATI, OHIO 45202**

PRINCIPAL DISPLAY PANEL - 20 Extended-Release Tablet Blister Pack Carton

COMPARE TO the active ingredients of
Mucinex[®] DM

NDC 30142-948-20

Kroger[®]

OUR PHARMACIST RECOMMENDED

Mucus Relief

ER DM

Guaifenesin 600 mg &

Dextromethorphan HBr 30 mg

Extended-Release

Tablets

EXPECTORANT &

COUGH SUPPRESSANT

12

HOUR

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

20 EXTENDED-RELEASE
TABLETS



Mucus Relief ER DM

Guaifenesin 600 mg & Dextromethorphan HBr 30 mg
Extended-Release Tablets
EXPECTORANT & COUGH SUPPRESSANT

COMPARE TO the active ingredients of
Mucinex® DM *See back panel

NDC 30142-948-20



Mucus Relief ER DM

Guaifenesin 600 mg &
Dextromethorphan HBr 30 mg
Extended-Release
Tablets
**EXPECTORANT &
COUGH SUPPRESSANT**

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

12 HOUR

actual
size

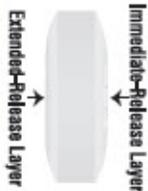


20 EXTENDED-RELEASE TABLETS



Mucus Relief ER DM
Guaifenesin 600 mg & Dextromethorphan HBr 30 mg
Extended-Release Tablets
EXPECTORANT & COUGH SUPPRESSANT

Tablet shown
actual size



PARENTS:

Learn about teen medicine abuse

www.StopMedicineAbuse.org

Lot No.

Expiration Date:

NON VARNISH





5229128

Drug Facts

Active ingredients (in each extended-release tablet)	Purposes
Dextromethorphan HBr 30 mg.....	Cough suppressant
Guaifenesin 600 mg.....	Expectorant

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.

Drug Facts (continued)

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 and older: 1 or 2 extended-release tablets every 12 hours; not more than 4 extended-release tablets in 24 hours
- children under 12 years of age: do not use

Other information

- Store between 20-25°C (68-77°F)

Inactive ingredients

carbomer homopolymer, colloidal silicon dioxide, hypromellose, magnesium stearate, maltodextrin, microcrystalline cellulose, povidone (K-30), stearic acid

Questions or comments?

1-800-632-6900
 You may also report side effects to this phone number.

**DISTRIBUTED BY THE KROGER CO.
 CINCINNATI, OHIO 45202**

PRODUCT OF INDIA

**QUALITY GUARANTEE
 800-632-6900 | www.kroger.com**

***All trademarks are property of their respective owners. This product is not affiliated with the makers/owners of Muclnex® DM.**

KEEP THE CARTON. IT CONTAINS IMPORTANT INFORMATION. SEE END PANEL FOR EXPIRATION DATE.



0322

GLUE - NO COATING



5229128

GUAIFENESIN AND DEXTROMETHORPHAN HBR

guaifenesin and dextromethorphan hbr tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30142-948
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
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01Z NK31)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
POVIDONE K30 (UNII: U725QWY32X)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	WHITE (off-white)	Score	no score
Shape	OVAL	Size	16mm
Flavor		Imprint Code	054
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30142-948-20	1 in 1 CARTON	05/23/2022	
1		20 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:30142-948-40	2 in 1 CARTON	05/23/2022	
2		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	ANDA214781	05/23/2022	

Labeler - Kroger Company (006999528)

Registrant - SUN PHARMACEUTICAL INDUSTRIES, INC. (146974886)

Establishment

Name	Address	ID/FEI	Business Operations
Sun Pharmaceutical Industries Limited		650456002	MANUFACTURE(30142-948)

Revised: 5/2022

Kroger Company