

GUAIFENESIN AND DEXTROMETHORPHAN HYDROBROMIDE- guaifenesin and dextromethorphan hydrobromide tablet, extended release
KROGER COMPANY

Guaifenesin and Dextromethorphan Hydrobromide

Drug Facts

<i>Active ingredients (in each extended-release tablet)</i>	<i>Purposes</i>
Dextromethorphan HBr 60 mg	Cough suppressant
Guaifenesin 1200 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 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 tablet every 12 hours; not more than 2 tablets in 24 hours
- children under 12 years of age: do not use

Other information

- **Tamper evident: Do not use if carton is open or if printed seal on blister is broken or missing.**
- store between 20-25°C (68-77°F)

Inactive ingredients

carbomer homopolymer type B; hypromellose, USP; magnesium stearate, NF; microcrystalline cellulose, NF; sodium starch glycolate, NF

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 - 14 Tablet Blister Pack Carton

COMPARE TO the active ingredients of
MAXIMUM STRENGTH MUCINEX[®] DM *See back panel

NDC 30142-706-14

Kroger[®]

OUR PHARMACIST RECOMMENDED

Maximum Strength

Mucus Relief
ER DM - Max

Guaifenesin 1200 mg &
Dextromethorphan HBr 60 mg
Extended-Release
Tablets

EXPECTORANT &
COUGH SUPPRESSANT

HOUR

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

actual
size

14 EXTENDED-RELEASE
TABLETS



Maximum Strength

Mucus Relief ER DM-Max

Guaifenesin 1200 mg & Dextromethorphan HBr 60 mg
Extended-Release Tablets
EXPECTORANT & COUGH SUPPRESSANT

COMPARE TO the active ingredients of
MAXIMUM STRENGTH MUCINEX® DM *See back panel

NDC 30142-706-14



Maximum Strength

Mucus Relief ER DM-Max

Guaifenesin 1200 mg &
Dextromethorphan HBr 60 mg
Extended-Release
Tablets

EXPECTORANT &
COUGH SUPPRESSANT

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

12
HOUR

actual
size



14 EXTENDED-RELEASE
TABLETS



Maximum Strength

Mucus Relief ER DM-Max

Guaifenesin 1200 mg & Dextromethorphan HBr 60 mg
Extended-Release Tablets
EXPECTORANT & COUGH SUPPRESSANT

PARENTS:

Learn about teen medicine abuse

www.StopMedicineAbuse.org

Lot No.

Expiration Date:

NON VARNISH





5207070

Drug Facts

**Active ingredients
(in each extended-
release tablet)**

Dextromethorphan HBr 60 mg.....Cough
suppressant
Guaifenesin 1200 mg.....Expectorant

Purposes

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 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 tablet every 12 hours; not more than 2 tablets in 24 hours
- children under 12 years of age: do not use

Other information

- Tamper evident: Do not use if carton is open or if printed seal on blister is broken or missing.
- store between 20-25°C (68-77°F)

Inactive ingredients

carbomer homopolymer type B; hypromellose, USP; magnesium stearate, NF; microcrystalline cellulose, NF; sodium starch glycolate, NF

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**

MADE IN ENGLAND

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

*All trademarks are property of their respective owners. MUCINEX is a registered trademark of RB HEALTH (US) LLC.

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



R0120

GLUE - NO COATING

0707070



GUAIFENESIN AND DEXTROMETHORPHAN HYDROBROMIDE

guaifenesin and dextromethorphan hydrobromide tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30 142-706
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 HOMO POLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	WHITE	Score	no score
Shape	OVAL	Size	22mm
Flavor		Imprint Code	xeunciM;1200;
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30 142-706-14	1 in 1 CARTON	09/05/2017	
1		14 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:30 142-706-28	2 in 1 CARTON	09/05/2017	
2		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
NDA	NDA021620	09/05/2017	

Labeler - KROGER COMPANY (006999528)

Establishment

Name	Address	ID/FEI	Business Operations
RECKITT BENCKISER HEALTHCARE INTERNATIONAL		220790262	MANUFACTURE(30 142-706) , LABEL(30 142-

