

LEADER MUCUS DM- dextromethorphan hbr, guaifenesin tablet, extended release

Cardinal Health 110, LLC. dba Leader

Cardinal Health Mucus DM Drug Facts

Active ingredients (in each extended-release tablet)

Dextromethorphan HBr 60 mg

Guaifenesin 1200 mg

Purposes

Cough suppressant

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

- **each tablet contains:** magnesium 25 mg
- do not use if printed foil under cap is broken or missing
- store between 20-25°C (68-77°F)

Inactive ingredients

carbomer homopolymer type B, copovidone, D&C yellow #10 aluminum lake, hypromellose, magnesium hydroxide, magnesium stearate, microcrystalline cellulose, silicon dioxide

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

Maximum Strength

Mucus-DM

Guaifenesin, 1200 mg

Dextromethorphan Hydrobromide, 60 mg

Extended-Release Tablets

Expectorant | Cough Suppressant

12 Hour

COMPARE TO MAXIMUM STRENGTH MUCINEX® DM active ingredients

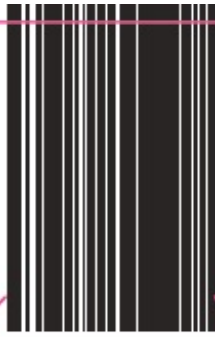
Controls Cough

Thins and Loosens Mucus

100% Money Back Guarantee

28 EXTENDED-RELEASE TABLETS

Actual Size



LEADER²TM

NDC 70000-0372-2

Maximum Strength

Mucus-DM

Guaifenesin, **1200 mg**
Dextromethorphan Hydrobromide, **60 mg**
Extended-Release Tablets
Expectorant | Cough Suppressant

12 Hour

Controls Cough
Thins and Loosens
Mucus

COMPARE TO
MAXIMUM STRENGTH
MUCINEX[®] DM
active ingredients*

100% Money
Back Guarantee

28 EXTENDED-RELEASE
TABLETS



Actual Size



LEADER²TM

Actual Size



LEADER²TM

NDC 70000-0372-2

Maximum Strength

Mucus-DM

Guaifenesin, **1200 mg**
Dextromethorphan
Hydrobromide, **60 mg**
Extended-Release Tablets
Expectorant
Cough Suppressant
12 Hour

28

EXTENDED-RELEASE TABLETS





12 Hour
Mucus-DM
Maximum Strength

LEADERTM

LEADERTM

Drug Facts

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

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

Drug Facts (continued)

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

- each tablet contains: magnesium 25 mg
- do not use if printed full under cap is broken or missing
- store between 20-25°C (68-77°F)

Inactive ingredients

carbomer homopolymer type B, copovidone, D&C yellow #10 aluminum lake, hypromellose, magnesium hydroxide, magnesium stearate, microcrystalline cellulose, silicon dioxide

Questions or comments?

1-800-710-9260

Gluten Free

Keep the carton. It contains important information.

*This product is not manufactured or distributed by Reckitt Benckiser LLC, owner of the registered trademark Mucinex®.

© 2018 Cardinal Health. All Rights Reserved. CARDINAL HEALTH, the Cardinal Health LOGO, LEADER, and the Leader LOGO are trademarks or registered trademarks of Cardinal Health. All other marks are the property of their respective owners.

CardinalHealthTM

DISTRIBUTED BY CARDINAL HEALTH
DUBLIN, OHIO 43017
www.myleader.com 1-800-200-6383
Essential to Care® Since 1979

All LEADERTM Brand Products Have A 100% Money Back Guarantee
Return to place of purchase if not satisfied.

PARENTS:

Learn about teen medicine abuse

www.StopMedicineAbuse.org

CIN 5441241 REV. 4/18



0 96295 13465 0

81230 E9 C1

LEADER MUCUS DM

dextromethorphan hbr, guaifenesin tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0372
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	60 mg

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
COPOVIDONE K25-31 (UNII: D9C330MD8B)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM HYDROXIDE (UNII: NBZ3QY004S)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	YELLOW (light)	Score	no score
Shape	OVAL	Size	22mm
Flavor		Imprint Code	L812
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0372-2	1 in 1 CARTON	05/07/2018	
1		28 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:70000-0372-1	1 in 1 CARTON	05/07/2018	
2		14 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207602	05/07/2018	

Labeler - Cardinal Health 110, LLC. dba Leader (063997360)