

**MAXIMUM STRENGTH GUAIFENESIN DM- guaifenesin, dextromethorphan
hbr tablet, extended release
Rugby Laboratories**

Drug Facts

Active ingredients (in each extended-release tablet)

Dextromethorphan HBr 60 mg

Guaifenesin 1200 mg

Purpose

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 regards for timing of meals
- adults and children 12 years of age 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 between 20° to 25°C (68° to 77°F)

Inactive ingredients

carbomer, colloidal silicon dioxide, D&Cyellow #10 aluminum lake, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone, talc

Questions or comments?

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

Principal Display Panel

Compare to the active ingredients in Maximum Strength Mucinex® DM*

Maximum strength

Mucus Relief DM

Guaifenesin | 1200 mg

Expectorant

Dextromethorphan HBr | 60 mg

Cough Suppressant

- 12-hour relief
- Controls Cough
- Thins & Loosens Mucus

Extended Release Tablets

*This product is not manufactured or distributed Reckitt Benckiser LLC, distributor of Maximum Strength Mucinex® DM.

TAMPER EVIDENT: DO NOT USE IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Distributed by:

Rugby Laboratories

17177 N Laurel Park Drive, Suite 233

Livonia, MI 48152

www.rugbylaboratories.com

Package Label

Drug Facts	
Active ingredients (in each extended-release tablet)	Purposes
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	
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■ 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.	
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■ 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 the 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	
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Other information ■ store between 20° to 25°C (68° to 77°F)	
Inactive ingredients carbomer, colloidal silicon dioxide, D&C yellow #10 aluminum lake, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone, talc	
Questions or comments? Call 1-800-645-2158	

*This product is not manufactured or distributed by Reckitt Benckiser LLC, distributor of Maximum Strength Mucinex® DM.

Re-order No. 370582
R-58
Rev. 05/19

Distributed by:
Rugby Laboratories
17177 N Laurel Park Drive, Suite 233
Livonia, MI 48152
www.rugbylaboratories.com



Maximum strength
Guaifenesin DM



NDC 0536-1213-88

Compare to the active ingredients in
Maximum Strength Mucinex® DM*

Maximum strength Guaifenesin DM

Guaifenesin 1200 mg
Expectorant

Dextromethorphan HBr 60 mg
Cough suppressant

- 12-hour relief
- Controls cough
- Thins and loosens mucus



Actual Size

14 Extended-release tablets

TAMPER EVIDENT: DO NOT USE IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Lot No.:

Exp. Date:

RUGBY Maximum Strength Guaifenesin DM

MAXIMUM STRENGTH GUAIFENESIN DM

guaifenesin, dextromethorphan hbr tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1213
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	60 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	1200 mg

Inactive Ingredients

Ingredient Name	Strength
CARBOMER 934 (UNII: Z135WT9208)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	yellow	Score	no score
Shape	OVAL	Size	22mm
Flavor		Imprint Code	AN039
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1213-88	14 in 1 CARTON	11/05/2018	09/28/2026
1		1 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
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ANDA

ANDA209692

11/05/2018

09/28/2026

Labeler - Rugby Laboratories (079246066)

Revised: 2/2026

Rugby Laboratories