

**MUCUS RELIEF DM EXTENDED RELEASE CAPLETS- guaifenesin, dextromethorphan  
hbr tablet**

**Rugby Laboratories, Inc.**

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**Drug Facts**

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

Dextromethorphan HBr 30 mg

Guaifenesin 600 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 condition.

**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 or 2 tablet every 12 hours; not more than 4 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&C yellow #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 Mucinex® DM\*

Mucus Relief DM ER

Guaifenesin 600 mg

Expectorant HBr 30 mg

Dextromethorphan HBr 30 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 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](http://www.rugbylaboratories.com)

# Package Label

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 Guaifenesin 600 mg.....Expectorant

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 ■ the impulse to cough to help you get to sleep

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**When using this product**, do not use more than directed.  
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**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).

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 Re-order No. 370580  
 R-58 Rev. 03/18  
 Distributed by:  
**Rugby Laboratories**  
 17177 N Laurel Park Drive, Suite 233  
 Livonia, MI 48152  
 www.rugbylaboratories.com

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**PARENTS:**  
 Learn about your medicine here  
 www.StopMedicineAbuse.org

Mucus Relief DM ER



NDC 0536-1161-34

Compare to the active ingredients in Mucinex® DM\*

**Mucus Relief DM ER**

Guaifenesin 600 mg  
 Expectorant

Dextromethorphan HBr 30 mg  
 Cough suppressant

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

20 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 Mucus Relief DM ER

### MUCUS RELIEF DM EXTENDED RELEASE CAPLETS

guaifenesin, dextromethorphan hbr tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-116 1
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CARBOMER 934 (UNII: Z135WT9208)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
TALC (UNII: 7SEV7J4R1U)	

## Product Characteristics

Color	YELLOW	Score	no score
Shape	OVAL	Size	16 mm
Flavor		Imprint Code	AN038
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1161-34	20 in 1 CARTON	12/13/2018	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0536-1161-37	40 in 1 CARTON	12/13/2018	
2		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
ANDA	ANDA209692	12/13/2018	

**Labeler** - Rugby Laboratories, Inc. (079246066)

Revised: 10/2019

Rugby Laboratories, Inc.