MUCUS RELIEF DM EXTENDED RELEASE CAPLETS- guaifenesin, dextromethorphan hbr tablet Rugby Laboratories, Inc.

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 under12 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&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 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:

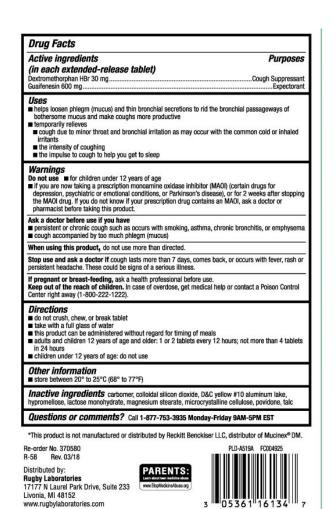
Rugby Laboratories

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Package Label





MUCUS RELIEF DM EXTENDED RELEASE CAPLETS

guaifenesin, dextromethorphan hbr tablet

Product Information		
Product Type	HUMAN OTC DRUG	Item Code (Source)

Route of Administration ORAL

Active Ingredient/Active Moiety	ve 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	

NDC:0536-1161

Inactive Ingredients		
Ingredient Name	Strength	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
CARBOMER 934 (UNII: Z135WT9208)		
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)		
POVIDONE (UNII: FZ 989GH94E)		
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)		
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)		
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)		
TALC (UNII: 7SEV7J4R1U)		

Product Characteristi	roduct Characteristics			
Color	yellow	Score	no score	
Shape	OVAL	Size	16mm	
Flavor		Imprint Code	AN038	
Contains				

P	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		
ANDA	ANDA209692	12/13/2018		

Labeler - Rugby Laboratories, Inc. (079246066)

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