

MUCUS RELIEF DM- guaifenesin, dextromethorphan hbr tablet
P & L Development, LLC

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 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 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 active ingredients in Mucinex® DM*

mucus relief dm

dextromethorphan HBr

cough suppressant

guaifenesin

expectorant

- 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:
 PL Developments
 200 Hicks Street
 Westbury, NY 11590

Package Label

<p>Drug Facts</p> <p>Active ingredients (in each extended-release tablet)</p> <p>Dextromethorphan HBr 30 mg.....Cough Suppressant Guaifenesin 600 mg.....Expectorant</p> <p>Purposes</p> <p>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</p> <p>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.</p> <p>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)</p> <p>When using this product, do not use more than directed.</p> <p>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.</p> <p>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).</p> <p>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 of age and older: 1 or 2 tablets every 12 hours; not more than 4 tablets in 24 hours ■ children under 12 years of age: do not use</p> <p>Other information ■ store between 20° to 25°C (68° to 77°F)</p> <p>Inactive ingredients carbomer, colloidal silicon dioxide, D&C yellow #10 aluminum lake, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone, talc</p> <p>Questions or comments? Call 1-877-753-3935 Monday-Friday 9AM-5PM EST</p> <p><small>*This product is not manufactured or distributed by Reckitt Benckiser LLC, distributor of Mucinex® DM.</small></p> <p><small>PLD-A519A FCO08148</small></p> <p><small>3 59726 73207 9</small></p> <p><small>Learn about teen medicine abuse www.StopMedicineAbuse.org</small></p>	<div style="display: flex; justify-content: space-between;"> <div style="text-align: center;">  <p style="writing-mode: vertical-rl; transform: rotate(180deg); font-size: 2em; font-weight: bold;">mucus relief dm</p> </div> <div style="text-align: center;">  </div> <div style="text-align: right;"> <p><small>Compare to active ingredients in Mucinex® DM*</small></p> <p><small>NDC 59726-733-06</small></p> </div> </div> <div style="text-align: center; margin-top: 20px;">  <p style="font-size: 1.5em; font-weight: bold;">mucus relief dm</p> <p>dextromethorphan HBr cough suppressant</p> <p>guaifenesin expectorant</p> <ul style="list-style-type: none"> • 12-hour relief • controls cough • thins and loosens mucus <p style="font-size: 1.2em; font-weight: bold; color: green;">6 extended-release tablets</p> <div style="display: flex; justify-content: center; align-items: center; margin-top: 10px;">  actual size </div> </div> <div style="text-align: center; margin-top: 20px;"> <p style="font-size: 0.8em; border: 1px solid black; padding: 2px; display: inline-block;">TAMPER EVIDENT: DO NOT USE IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.</p> <p style="font-size: 0.8em; border: 1px solid black; padding: 2px; display: inline-block;">KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.</p> </div> <div style="margin-top: 20px;"> <p>Lot No.: _____</p> <p>Exp. Date: _____</p> </div>
---	--

READYinCASE Mucus Relief DM

<p>MUCUS RELIEF DM guaifenesin, dextromethorphan hbr tablet</p>			
<p>Product Information</p>			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59726-733

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: 9D2RT19KYH) (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	16mm
Flavor		Imprint Code	AN038
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59726-733-40	40 in 1 CARTON	12/31/2018	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:59726-733-06	6 in 1 CARTON	12/31/2018	
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	12/31/2018	

Revised: 2/2022

P & L Development, LLC