MUCUS RELIEF DM MAXIMUM STRENGTH- dextromethorphan hbr, guaifenesin liquid Cardinal Health (Leader) 70000

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active ingredients (in each 20 mL)

Dextromethorphan HBr 20 mg Guaifenesin 400 mg

Purposes

Cough suppressant

Expectorant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of botherosme 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

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 that occurs with 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 headache that lasts. 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 (1-800-222-1222) right away.

Directions

- do not take more than 6 doses in any 24-hour period
- measure only with dosing cup provided. Do not use any other dosing device.
- keep dosing cup with product
- mL = milliliter
- dose as follows or as directed by a doctor
- adults and children 12 years of age and older: 20 mL every 4 hours
- children under 12 years of age: do not use

Other information

- each 20 mL contains: sodium 20 mg
- store between 20-25°C (68-77°F). Do not refrigerate.

Inactive ingredients

citric acid, disodium EDTA, FD&C red #40, flavor, glycerin, propyl gallate, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol, sucralose, xanthan gum

Principal Display Panel

COMPARE TO MAXIMUM STRENGTH MUCINEX® FAST-MAX® DM MAX active ingredient

Maximum Strength Mucus Relief DM

Dextromethorphan HBr 20 mg

Guaifenesin 400 mg

Cough Suppressant | Expectorant

For Ages 12 Years and Over

Controls Cough

Relieves Chest Congestion

Thin & Loosens Mucus 4 Hour Dosing

Questions or comments? Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

FL OZ (mL)

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

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL AROUND OR UNDER CAP IS BROKEN OR MISSING.

DISTRIBUTED BY CARDINAL HEALTH DUBLIN, OHIO 43017

Package Label



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PLD-A409A LB003948

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......Cough suppressant
Gualfenesin 400 mg......Expectorant

Purposes

PEEL CORNER FOR MORE DRUG FACTS

Drug Facts (continued)

Uses

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- 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

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Drug Facts (continued)

Ask a doctor before use if you have

 persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema

Monday-Friday 9AM-5PM EST

6 FL OZ (177 mL)

 cough that occurs with too much phlegm (mucus)

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

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If pregnant or breast-feeding, ask a health professional before use.

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PEEL CORNER FOR MORE DRUG FACTS

LEADER Maximum Strength Mucus Relief DM

dextromethorphan hbr, guaifenesin liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0565	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 20 mL	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg in 20 mL	

Inactive Ingredients		
Ingredient Name	Strength	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)		
EDETATE CALCIUM DISODIUM (UNII: 25IH6R4SGF)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
GLYCERIN (UNII: PDC6A3C0OX)		
PROPYL GALLATE (UNII: 8D4SNN7V92)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
SODIUM CITRATE (UNII: 1Q73Q2JULR)		
SORBITOL (UNII: 506T60A25R)		
SUCRALOSE (UNII: 96K6UQ3ZD4)		
XANTHAN GUM (UNII: TTV12P4NEE)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000- 0565-1	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/30/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	04/30/2020		

Labeler - Cardinal Health (Leader) 70000 (063997360)

Revised: 11/2022