CVS MUCUS RELIEF DM AND OVERNIGHT COLD AND FLU- dextromethorphan hbr, guaifenesin, acetaminophen and triprolidine hcl CVS

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.

Maximum Strength Mucus Relief DM and Overnight Cold & Flu Value Pack Drug Facts

Active ingredients (in each 20 mL) Maximum Strength Mucus Relief DM Max	Purposes
Dextromethorphan HBr 20 mg	Cough suppressant
Guaifenesin 400 mg	Expectorant
Active ingredients (in each 20 mL) Nighttime Cold & Flu	Purposes
Acetaminophen 650 mg	Pain reliever/fever reducer
Dextromethorphan HBr 20 mg	Cough suppressant
Triprolidine HCl 2.5 mg	Antihistamine

Uses

MAXIMUM STRENGTH MUCUS RELIEF DM

- 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

• 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 that 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 sings of a serious condition.

If pregnancy 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 Centre right away at 1-800-222-1222

Directions

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

Other information

- each 20 mL contains: sodium 8 mg
- low sodium
- store at room temperature
- do not refrigerate
- dosing cup provided

Inactive ingredients (Maximum strength mucus relief DM)

anhydrous citric acid, edetate disodium, FD&C Blue No.1, FD&C Red No. 40, flavors, potassium citrate, propylene glycol, propyl gallate, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum

Uses (Nighttime Cold and Flu)

- temporarily relieves these common cold and flu symptoms:
- cough
- minor aches and pains
- sore throat
- headache
- runny nose
- sneezing
- itching of the nose or throat
- itchy, watery eyes due to hay fever
- temporarily reduces fever
- controls cough to help you get to sleep

Warnings

Liver warnings: This product contains acetaminophen. Severe liver damage may occur if you take\

- more than 4000 mg in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks daily while using this product

If pregnant or breast feeding

Ask a health professional before use

Keep Out of Reach of Children

Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Centre right away at 1-800-222-1222.

Quick medical attention is critical for adults as well as for children, even if you do not notice any signs

Directions

- do not take more than directed (see overdose warnings
- do not take more than 4 doses in any 24-hour period
- measure only with dosing cup provided
- do not use dosing cup with other products
- dose as follows or as directed by a doctor
- adults and children 12 years of age and older: 20 ml in dosing cup provided every 4 hours
- children under 12 years of age: do not use

Other Information

- each 20 mL contains: sodium 10 mg
- low sodium
- store at room temperature

do not refrigerate

Inactive ingredients (Overnight Cold & Flu)

anhydrous citric acid, ascorbic acid, edetate disodium, FD&C Blue No. 1, FD&C Red No. 40, flavors, glycerin, propyl gallate, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol, sucralose, xanthan gum

Questions or comments?

(1-866-467-2748)

PRINCIPAL DISPLAY PANEL - Kit Carton

VALUE PACK

NDC 69842-696-12

Compare to the active ingredients Maximum Strength Mucinex® Fast Max® DM Max*

Mucus Relief DM

Dextromethorphan HBr • Cough Suppressant Guaifenesin • Expectorant MAXIMUM STRENGTH

MULTI-SYMPTOM

- Controls Cough
- Relieves chest congestion
- Thins & loosens mucus
- 4 hour dosing

For Ages 12+

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

Compare to Mucinex® Nightshift Cold & Flu Active Ingredients**

Overnight Cold & Flu

ACETAMINOPHEN • PAIN RELIEVER/FEVER REDUCER DEXTROMETHORPHAN HBR • COUGH SUPPRESSANT

TRIPROLIDINE HCL • ANTIHISTAMINE

Night Time

Relief for Better Morning

Maximum Strength per 4-hour dose

Cough

- Fever
- Sore Throat
- Runny Nose
- Sneezing

For Ages 12+

2 - 6 FL OZ (180 mL) BOTTLES / TOTAL 12 FL OZ (360 mL)

^{††}These product is not manufactured or distributed by Reckitt Benckister Health, distributor of Maximum Strength Mucinex® Fast Max© DM Max & Mucinex© Nightshift Cold & Flu.

DO NOT TAKE ADULT DM MAXIMUM & NIGHTTIME COLD & FLU LIQUIDS AT THE SAME TIME.

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

See bottle for full labeling

Distributed By:

CVS Pharmacy, Inc.

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Woonsocket, RI 02895

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V-12431

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CVS MUCUS RELIEF DM AND OVERNIGHT COLD AND FLU

dextromethorphan hbr, guaifenesin, acetaminophen and triprolidine hcl kit

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:69842-696

l	Packaging				
	# Item Code Package Description		Marketing Start Date	Marketing End Date	
	1	NDC:69842-696- 12	1 in 1 CARTON; Type 0: Not a Combination Product	03/30/2020	

Quant	Quantity of Parts			
Part # Package Quantity		Total Product Quantity		
Part 1	1 BOTTLE	180 mL		
Part 2	1 BOTTLE	180 mL		

Part 1 of 2

MAXIMUM STRENGTH MUCUS RELIEF DM

dextromethorphan hbr and guaifenesin solution

Product Information

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 DISODIUM (UNII: 7FLD91C86K)			
FD&C Blue No. 1 (UNII: H3R47K3TBD)			
FD&C Red No. 40 (UNII: WZB9127XOA)			
POTASSIUM CITRATE (UNII: EE90ONI6FF)			
propylene glycol (UNII: 6DC9Q167V3)			
propyl gallate (UNII: 8D4SNN7V92)			

water (UNII: 059QF0KO0R)	
sodium benzoate (UNII: OJ245FE5EU)	
sorbitol (UNII: 506T60A25R)	
sucralose (UNII: 96K6UQ3ZD4)	
xanthan gum (UNII: TTV12P4NEE)	

Product Characteristics			
Color	BLUE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

ı	Pa	Packaging			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1		180 mL in 1 BOTTLE; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part341	03/30/2020			

Part 2 of 2

OVERNIGHT COLD AND FLU

acetaminophen, dextromethorphan hbr and triprolidine hcl solution

Product Information

Route of Administration ORAL

Active Ingredient/Active Moiety Basis of Strength Ingredient Name Strength 650 mg Acetaminophen (UNII: 36209ITL9D) (Acetaminophen - UNII:36209ITL9D) Acetaminophen in 20 mL **DEXTROMETHORPHAN HYDROBROMIDE** (UNII: 9D2RTI9KYH) DEXTROMETHORPHAN 20 mg (DEXTROMETHORPHAN - UNII:7355X3ROTS) in 20 mL **HYDROBROMIDE** TRIPROLIDINE HYDROCHLORIDE (UNII: YAN7R5L890) (TRIPROLIDINE -TRIPROLIDINE 2.5 mg in 20 mL UNII:2L8T9S52QM) **HYDROCHLORIDE**

Inactive Ingredients

Ingredient Name	Strength
anhydrous citric acid (UNII: XF417D3PSL)	
edetate disodium (UNII: 7FLD91C86K)	
FD&C Blue No. 1 (UNII: H3R47K3TBD)	
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, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
sorbitol (UNII: 506T60A25R)	
sucralose (UNII: 96K6UQ3ZD4)	
xanthan gum (UNII: TTV12P4NEE)	

Product Characteristics			
Color	BLUE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

ı	Pā	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1		180 mL in 1 BOTTLE; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	03/30/2020		

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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	03/30/2020		
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Labeler - CVS (062312574)

Revised: 9/2023 CVS