

**DAYTIME AND NIGHTTIME COUGH AND CHEST CONGESTION CHILDRENS-  
dextromethorphan hbr, guaifenesin, chlorpheniramine maleate  
CVS Pharmacy**

*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.*

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**CVS Health Non-Drowsy Children's Daytime & Night-Time Cough and Chest  
Congestion DM**

**Active ingredients Day Time (in each 5 mL)**

Dextromethorphan HBr USP 5 mg

Guaifenesin. USP 100 mg

**Active ingredients for Nighttime (in each 10 mL)**

Chlorpheniramine maleate, USP 2 mg

Dextromethorphan HBr USP 15 mg

**Purposes for Day Time**

Cough suppressant

Expectorant

**Purpose for Night Time**

Antihistamine

Cough suppressant

**Uses**

**DAYTIME**

- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes

**NIGHTTIME**

- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold
- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose
- sneezing
- itching of the nose or throat
- itchy, watery eyes

## **Warnings**

### **Do not us**

#### **DAYTIME**

- 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.

#### **NIGHTTIME**

- to sedate a child or to make a child sleepy
- 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**

#### **DAYTIME**

- cough that occurs with too much phlegm (mucus)
- cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis or emphysema

#### **NIGHTTIME**

- trouble urinating due to an enlarges prostate gland
- glaucoma
- a cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis or emphysema

### **Ask a doctor or pharmacist before use if you are**

#### **NIGHTTIME**

taking sedatives or tranquilizers.

### **When using this product**

#### **NIGHTTIME**

- **do not use more than directed.**

- marked drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

**Stop use and ask a doctor if**

**DAYTIME**

- cough last more than 7 days, comes back or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.

**NIGHTTIME**

- cough last more than 7 days, comes back or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.

**If pregnant or breast-feeding,**

**DAYTIME**

ask a health professional before use.

**NIGHTTIME**

ask a health professional before use

**Keep out of reach of children.**

**DAYTIME**

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

**NIGHTTIME**

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away

**Directions**

**DAYTIME**

- measure only with dosing cup provided.
- keep dosing cup with product
- mL= milliliter
- do not take more than 6 doses in any 24-hour period

age	dose
Children under 4 years	Do not use
Children 4 to under 6 years	5 mL every 4 hours
Children 6 to under 12 years	10 mL every 4 hours
Adults and children 12 years and older	20 mL every 4 hours

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## NIGHTTIME

- measure only with dosing cup provided.
- keep dosing cup with product
- mL= milliliter
- do not take more than 4 doses in any 24-hour period

age	dose
Children under 6 years	Do not use
Children 6 to under 12 years	10 mL every 6 hours
Adults and children 12 years and older	20 mL every 6 hours

## Other information

### DAYTIME

- each 5 mL contains: **sodium 3 mg**
- store at room temperature. Do not refrigerate
- contain low sodium
- **do not use if printed seal under cap is torn or missing**

### NIGHTTIME

- each 10 mL contains: **sodium 3 mg**
- store at room temperature. Do not refrigerate
- contain low sodium
- **do not use if printed seal under cap is torn or missing**

## Inactive ingredients

### *Inactive ingredients for Day Time*

anhydrous citric acid, edetate disodium, FD&C Blue # 1, FD&C Red # 40, natural and artificial flavors, potassium citrate, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum

### *Inactive ingredients for Night Time*

anhydrous citric acid, FD&C Red # 40, natural and artificial flavors, potassium sorbate, potassium citrate, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose

## Questions or comments?

**1-866-467-2748**

## Principal Display Panel

**Compare to the active ingredients in Children's Robitussin® Cough & Chest Congestion DM\***

**Non-Drowsy**

**Children's**

**Cough & Chest Congestions DM**

**Each 5 mL dose of oral solution contains:**

DEXTROMETHORPHAN HBr, USP 5 mg

Cough suppressant

GUAIFENESIN, USP 100 mg

Expectorant

**Relieves**

- Chest congestion/mucus
- Cough

**For Ages 4 and over**

Grape Flavor

Naturally and Artificially Flavored

Dosage cup included

TWO 4 FL OZ (118 mL) BOTTLES TOTAL - 8 FL OZ (236 mL)

**Compare to the active ingredients in Children's Robitussin® Nighttime Cough DM\***

**NDC# 69842-657-08**

**Children's**

**Nighttime Cough DM**

**Each 10 mL dose of oral solution contains:**

**CHLORPHENIRAMINE MALEATE, USP 2 mg**

Antihistamine

DEXTROMETHORPHAN HBr, USP 15 mg

Cough suppressant

**Relieves**

- Cough up to 8 hours
- Runny nose

Alcohol free

**For Ages 6 & over**

**Fruit Punch Flavor**

# Naturally and Artificially Flavored

## Dosage cup included

TWO 4 FL OZ (118 mL) BOTTLES TOTAL - 8 FL OZ (236 mL)

\*This product is not manufactured or distributed by Pfizer, owner of the registered trademarks Children's Robitussin<sup>®</sup> Cough + Chest Congestion DM and Children's Robitussin<sup>®</sup> Nighttime Cough DM.

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# DAYTIME AND NIGHTTIME COUGH AND CHEST CONGESTION CHILDRENS

dextromethorphan hbr, guaifenesin, chlorpheniramine maleate kit

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69842-657
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## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-657-08	1 in 1 KIT; Type 0: Not a Combination Product	02/19/2019	

## Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	118 mL
Part 2	1 BOTTLE	118 mL

## Part 1 of 2

### DAYTIME COUGH AND CHEST CONGESTION GRAPE FLAVOR

dextromethorphan hbr, guaifenesin liquid

## Product Information

<b>Route of Administration</b>	ORAL
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## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg in 5 mL
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>POTASSIUM CITRATE</b> (UNII: EE90ONI6FF)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	

<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

### Product Characteristics

<b>Color</b>	PURPLE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	GRAPE	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	02/19/2019	

## Part 2 of 2

### NIGHT TIME COUGH DM FRUIT PUNCH

chlorpheniramine maleate, diphenhydramine hbr liquid

### Product Information

<b>Route of Administration</b>	ORAL
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### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>CHLORPHENIRAMINE MALEATE</b> (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2 mg in 10 mL
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg in 10 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	



<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>POTASSIUM CITRATE</b> (UNII: EE90ONI6FF)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	

### Product Characteristics

<b>Color</b>	RED	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	FRUIT PUNCH	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	02/19/2019	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	02/19/2019	

**Labeler** - CVS Pharmacy (062312574)