DAYTIME AND NIGHTTIME COUGH AND CHEST CONGESTION CHILDRENSdextromethorphan 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.

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

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 $^{\mbox{\scriptsize B}}$ 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 $^{\ensuremath{\mathbb{R}}}$ 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[®] Cough + Chest Congestion DM and Children's Robitussin[®] Nighttime Cough DM.

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DAYTIME AND NIGHTTIME COUGH AND CHEST CONGESTION CHILDRENS

dextromethorphan hbr, guaifenesin, chlorpheniramine maleate kit

Product Inform	nation						
Product Type	HUMAN OTC DRUG Item Code (Source)			ce)	NDC:69842	2-657	
Packaging							
# Item Code	Package Description Marketin				eting Start Date		ting End ate
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Quantity of Pa Part #		.		Та	tal Product (Quentity	
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Part 2 1 BOTTLE			18 mL				
Part 1 of 2							
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_	DUGH AND C an hbr, guaifenesir		NGES	STION	GRAPE F	LAVOR	
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SODIUM BENZ		<00R)						
			FE5EU)					
SORBITOL (UN								
SUCRALOSE (
XANTHAN GUI	M (UNII:	TTV12P4NE	E)					
Product Cl	haract	teristics						
Color								
Shape	Size							
Flavor								
Contains								
Packaging								
# Item		Pack	age Description		Mark	eting Start		ting End
"Code						Date	D	ate
1	118 m Produc		LE; Type 0: Not a Comb	pination				
Marketir	ng In	format	tion					
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OTC monograph final part341								
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		part341			02/19	/2019		
Part 2 of	f 2				02/19	/2019		
Part 2 of NIGHT T	f 2 IME (COUGH	I DM FRUIT F		02/19	/2019		
Part 2 of NIGHT T chlorphenira	f 2 IME (amine r	COUGH maleate, c	I DM FRUIT F liphenhydramine hb		02/19	/2019		
Part 2 of NIGHT T	f 2 IME (amine r	COUGH maleate, c			02/19	/2019		
Part 2 of NIGHT T chlorphenira	f 2 IME (amine r	COUGH maleate, c ation			02/19	/2019		
Part 2 of NIGHT T chlorphenira Product In	f 2 IME (amine r aforma minist	COUGH maleate, c ation ration	liphenhydramine ht		02/19	/2019		
Part 2 of NIGHT T chlorphenira Product In Route of Ad	f 2 IME (amine r aforma minist	COUGH maleate, c ation ration	liphenhydramine ht		02/19	/2019 Basis of St	rength	Strengt
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FD&C RED NO	. 40 (UI	NII: WZB9127XOA)				
POTASSIUM S	ORBAT	E (UNII: 1VPU26JZZ4)				
POTASSIUM C	ITRATE	(UNII: EE90ONI6FF)				
PROPYLENE G	LYCOL	(UNII: 6DC9Q167V3)				
WATER (UNII: C)59QF0k	(O0R)				
SODIUM BENZ	OATE (UNII: OJ245FE5EU)				
SORBITOL (UN	II: 506T	60A25R)				
SUCRALOSE (U	JNII: 96	(6UQ3ZD4)				
Product Ch	aract	eristics				
Color		RED	S	core		
Shape			S	ize		
Flavor		FRUIT PUNCH	h	mprint Code		
Contains						
Packaging						
# Item Code		Package Des	cription	Marketing Start Date	Marketing End Date	
1	118 mL in 1 BOTTLE; Type 0: Not a Combination Product					
Marketin	ig In	formation				
Marketin Categor	g	Application Num	ber or Monograph ation	Marketing Start Date	Marketing End Date	
OTC monograp	-			02/19/2019		
Marketin	g In	formation				
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Labeler - CVS Pharmacy (062312574)

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