NIGHTTIME COUGH- dextromethorphan hydrobromide, doxylamine succinate solution CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED

CVS Pharmacy, Inc. Nighttime Cough Drug Facts

Active ingredients (in each 20 mL)

Dextromethorphan HBr, USP 30 mg

Doxylamine succinate, USP 12.5 mg

Purposes

Cough suppressant

Antihistamine

Uses

- 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
- itchy, watery eyes
- itching of the nose or throat
- controls the impulse to cough to help you sleep

Warnings

Do not use

- 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

- trouble urinating due to an enlarged prostate gland
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis

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

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers

When using this product

- 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

cough lasts for more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. A persistent cough may be a sign of a serious condition.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

Directions

- 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
- this adult product is not intended for use in children under 12 years of age

age	dose	
adults and children 12 years and over	20 mL every 6 hours	
children under 12 years	do not use	

Other information

- each 20 mL contains: sodium 11 mg
- store at 20-25°C (68-77°F)

Inactive ingredients

anhydrous citric acid, benzoic acid, benzyl alcohol, carboxymethylcellulose sodium, FD&C blue #1, FD&C red #40, flavor, glycerin, menthol, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucralose, xanthan gum

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

CVSHealth_®

ADULT

MAXIMUM STRENGTH

NIGHTTIME COUGH

DEXTROMETHORPHAN HBr

Cough Suppressant

DOXYLAMINE SUCCINATE

Antihistamine

MULTI-SYMPTOM RELIEF

Controls cough

Relieves runny nose & sneezing

See New Dosing

Compare to the active ingredients in Robitussin $^{\circledR}$ Maximum Strength Nighttime Cough DM

4 FL OZ (118 mL)

Raspberry, Blackberry & Menthol Flavor



DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING.

Drug Facts

Active ingredients Purpost (in each 20 mL) Dextromethorphan HBr, USP 30 mg......Cough suppress Doxylamine succinate, USP 12.5 mg.......Antihistami Purposes

MULTI-SYMPTOM RELIEF

NICHTIME MAXIMUM STRENGTH

CVSHealth.

Antih istamin e DOXYLA MINE SUCCINATE Cough Suppressant **ДЕХТЯОМ ЕТНОЯРНА И НВ**Г

CONCH

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- controls the impulse to cough to help you sleep
- Warnings

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- Ask a doctor before use if you have trouble urinating due to an enlarged prostate gland
- cough that occurs with too much phleam (mucus) a breathing problem such as emphysema or chronic bronchitis
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers
- When using this product

 do not use more than directed
 marked drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase
- be careful when driving a motor vehicle or operating machinery

 excitability may occur, especially in children
- Stop use and ask a doctor if cough lasts for more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. A persistent cough may be a sign of a serious condition.

Drug Facts (continued)

If pregnant or breast-feeding, ask a health professiona

Defore 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

- 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 this adult product is not intended for use in child under 12 years of age

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Other information

■ each 20 mL contains: sodium 11 mg ■ store at 20-25°C (68-77°F)

Inactive ingredients anhydrous citric acid, benzoic acid, benzyl alcohol, carboxymethycellulose sodium, FNAC ben #1. FNAC red #40, flavor, glycerin, menthol, polyethylene glycol, propylene glycol, purified water, sodium bencode, sorbitol solution, sucralose, santhan gum

Questions or comments? 1-800-719-9260

[†]This product is not manufactured or distributed by Haleon, distributor of Robitussin[®] Maximum Strength Nighttime Cough DM.





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NIGHTTIME COUGH

See New Dosing

Compare to the active

Nighttime Cough DM†

4 FL OZ

(118 mL)

ingredients in Robitussin^e Maximum Strength

Raspberry, Blackberry & Menthol Flavor

dextromethorphan hydrobromide, doxylamine succinate solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51316-062
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 20 mL	
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 20 mL	

Inactive Ingredients	
Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K6790BS311)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics			
Color	RED	Score	
Shape		Size	
Flavor	FRUIT	Imprint Code	
Contains			

Packaging						
# Item Code	Package Description	Marketing Start Date	Marketing End Date			
NDC:51316-062- 26	1 in 1 CARTON	06/12/2024				
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 Drug	M012	06/12/2024		

Labeler - CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED (062312574)

Revised: 10/2024

CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED