

**NIGHTTIME COLD AND COUGH CHILDRENS- diphenhydramine hcl,
phenylephrine hcl liquid
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.

Drug Facts

Active ingredients (in each 5 mL)

Diphenhydramine HCl 6.25 mg

Phenylephrine HCl 2.5 mg

Purposes

Antihistamine/Cough suppressant

Nasal decongestant

Uses

- temporarily relieves
 - sneezing
 - runny nose
 - itchy nose or throat
 - itchy, watery eyes due to hay fever
 - nasal and sinus congestion
 - cough due to minor throat and bronchial irritations as may occur with a cold

Warnings

Do not use

- in a child under 4 years of age
- in a child who is 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 child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.
- with any other product containing diphenhydramine, even one used on skin
- for the purpose of making your child sleepy

Ask a doctor before use if the child has

- heart disease
- high blood pressure
- thyroid disease

- diabetes
- glaucoma
- cough that occurs with too much phlegm (mucus)
- chronic cough that lasts, or as occurs with asthma
- a breathing problem such as chronic bronchitis

Ask a doctor or pharmacist before use if the child is

taking sedatives or tranquilizers

When using this product,

- **do not exceed recommended dosage**
- marked drowsiness may occur
- excitability may occur, especially in children
- sedatives and tranquilizers may increase drowsiness

Stop use and ask a doctor if

- nervousness, dizziness or sleeplessness occurs
- symptoms do not improve within 7 days or occur with a fever
- cough persists for more than 7 days, comes back or occurs with fever, rash or persistent headache.

These could be signs of a serious condition.

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 give more than 6 doses in 24 hours unless directed by a doctor.
- measure only with dosing cup provided Do not use any other dosing device
- keep dosing cup with product
- mL= milliliter
- shake well before using

Age	Dose
children 6 to under 12 years of age	10 mL every 4 hours
children 4 to under 6 years of age	do not use unless directed by a doctor
children under 4 years	do not use

Other Information

- **each 5 mL contains:** sodium 3 mg
- store between 20-25°C (68-77°F). Do not refrigerate.

- protect from light

Inactive ingredients

acesulfame potassium, anhydrous citric acid, EDTA disodium, FD&C blue #1, FD&C red #40, flavor, maltitol, propylene glycol, purified water, sodium benzoate, trisodium citrate dihydrate

Questions or comments?

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

Principal Display Panel

Children's

Nighttime Cold & Cough

DIPHENHYDRAMINE HCl Antihistamine; Cough suppressant

PHENYLEPHRINE HCl Nasal decongestant

Relieves:

- Cough
- Runny, stuffy nose
- Itchy throat

Alcohol free

For Ages 6 to 11 Years

Grape Flavor

FL OZ (mL)

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

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Package Label

Drug Facts (continued)

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PLD-8320E L8005843



Children's Nighttime Cold & Cough

NDC 69842-379-04

DIPHENHYDRAMINE HCl
 Antihistamine; Cough suppressant
PHENYLEPHRINE HCl
 Nasal decongestant

Relieves:

- Cough
- Runny, stuffy nose
- Itchy throat

Alcohol free
For Ages 6 to 11 Years Grape Flavor



4 FL OZ (118 mL)

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CVS HEALTH Children's Nighttime Cold & Cough

NIGHTTIME COLD AND COUGH CHILDRENS

diphenhydramine hcl, phenylephrine hcl liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-379
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII: 8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	6.25 mg in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
MALTITOL (UNII: D65DG142WK)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-379-04	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/30/2018	04/30/2025

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	04/30/2018	04/30/2025

Labeler - CVS Pharmacy (062312574)

Revised: 1/2023

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