

CVS HEALTH NIGHTTIME SLEEP-AID- diphenhydramine hydrochloride liquid
CVS Pharmacy, Inc.

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 Nighttime Sleep-Aid 12 FL OZ

Drug Facts

Active ingredient (in each 30 mL dose cup or 2 tablespoons)

Diphenhydramine HCl 50 mg

Purpose

Nighttime sleep-aid

Uses

- for the relief of occasional sleeplessness
- reduces time to fall asleep if you have difficulty falling asleep

Warnings

Do not use

- for children under 12 years of age
- with any other product containing diphenhydramine, even one used on skin
- with other drugs that cause drowsiness such as antihistamines and nighttime cold/flu products

Ask a doctor before use if you have

- a breathing problem such as asthma, emphysema, or chronic bronchitis
- glaucoma
- difficulty in urination due to enlargement of the prostate gland
- heart disease

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers or any other sleep- aid.

When using this product

- avoid alcoholic beverages and other drugs that cause drowsiness
- drowsiness will occur
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if sleeplessness persists continuously for more than two weeks. Insomnia may be a symptom of serious underlying medical illness.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

Overdose warning:

Taking more than directed can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away. 1-800-222-1222

Directions

- take only one dose per day (24 hours) – see Overdose warning
- measure with dosing cup provided

adults & children 12 yrs & over	One Dose = 30 mL (2 tablespoons) at bed time if needed or as directed by a doctor
Children under 12 yrs	Do not use

Other information

- each 30 mL dose (2 tablespoons) contains: **sodium 23 mg**
- store at room temperature
- protect from light. Does not meet USP <671>.

Inactive ingredients

anhydrous citric acid, FD&C blue 1, FD&C red 40, flavor, glycerin, potassium citrate, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum.

PRINCIPAL DISPLAY PANEL

CVS Health TM

Compare to the active ingredient in ZzzQuilTM Nighttime Sleep-Aid*

NDC 59779-893-12

SEE NEW WARNINGS

Alcohol Free

Nighttime

Sleep-Aid

DIPHENHYDRAMINE HCL

Non-habit forming
Not for treating cold or flu

Berry Flavor

Naturally & artificially flavored

12 FL OZ (354 mL)

FAILURE TO FOLLOW THESE WARNINGS COULD RESULT IN SERIOUS CONSEQUENCES.

TAMPER EVIDENT: DO NOT USE IF PRINTED SHRINK BAND IS MISSING OR BROKEN

*This product is not manufactured or distributed by Proctor & Gamble, the distributor of ZzzQuil™.

Distributed by: CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

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Money Back Guarantee

TAMPER EVIDENT: DO NOT USE IF PRINTED SHRINK BAND IS MISSING OR BROKEN

Drug Facts (continued)	
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LOT: _____

EXP: _____

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CVS HEALTH NIGHTTIME SLEEP-AID

diphenhydramine hydrochloride liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-893	
Route of Administration	ORAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)		DIPHENHYDRAMINE HYDROCHLORIDE	50 mg in 30 mL	
Inactive Ingredients				
Ingredient Name			Strength	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
GLYCERIN (UNII: PDC6A3C0OX)				
POTASSIUM CITRATE (UNII: EE90ONI6FF)				
WATER (UNII: 059QF0KO0R)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
SORBITOL (UNII: 506T60A25R)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
XANTHAN GUM (UNII: TTV12P4NEE)				
Product Characteristics				
Color	PURPLE	Score		
Shape		Size		
Flavor	BERRY	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-893-12	354 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/11/2015	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part338	02/11/2015		

Labeler - CVS Pharmacy,Inc. (062312574)

