

**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 Value Twin Pack 2 Bottles 12 FL OZ Each

Drug Facts

**Active ingredient
(in each 30 mL)**

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 contains:** potassium 5mg; sodium 10 mg
- store at room temperature

Inactive ingredients

anhydrous citric acid, FD&C Blue No. 1, FD&C Red No. 40, flavor, glycerin, potassium citrate, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum.

PRINCIPAL DISPLAY PANEL

VALUE TWIN PACK

CVS Health™

Compare to the active ingredient in ZzzQuil™ Nighttime Sleep-Aid*

NDC 59779-893-24

SEE NEW WARNINGS

Alcohol Free

Nighttime

Sleep-Aid

DIPHENHYDRAMINE HCL

Non-habit forming
Not for treating cold or flu

Berry Flavor

Naturally & artificially flavored

2 BOTTLES

12 FL OZ (354 mL) EACH;

24 FL OZ (708 mL) TOTAL

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™ Nighttime Sleep-Aid.

Distributed by: **CVS Pharmacy, Inc.**

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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:59779-893-24	2 in 1 PACKAGE, COMBINATION	07/14/2016	
1		354 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	part338	07/14/2016	

Labeler - CVS Pharmacy,Inc. (062312574)

