

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

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 at 1-800-222-1222.

Directions

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

adults & children 12yrs & 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 5 mg; sodium 10 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™

NDC 59779-893-06

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

Alcohol Free

Nighttime

Sleep-Aid

DIPHENHYDRAMINE HCl

Non-habit forming

Not for treating cold or flu

Berry Flavor

Naturally and Artificially Flavored

6 FL OZ (177 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 Procter & Gamble, the distributor of ZzzQuil®

Distributed by: CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

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V-30486

CVS® Quality

Money Back Guarantee

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

Drug Facts (continued)

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers.

When using this product ■ avoid alcoholic beverages

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.

CVS Quality Money Back Guarantee

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LOT: _____

EXP: _____

0 50428 27651 8

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

Alcohol Free
Nighttime
Sleep-Aid

DIPHENHYDRAMINE HCl

Non-habit forming
Makes you fall asleep fast

Not for pain. Not for colds. Just for sleep.

6 FL OZ (177 mL) Berry Flavor



PEEL BACK FOR DRUG FACTS

Drug Facts

Active ingredient (in each 30 mL dose cup)	Purpose
Diphenhydramine HCl 50 mg.....	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

Ask a doctor before use if you have
■ a breathing problem such as emphysema, or chronic bronchitis
■ glaucoma
■ difficulty in urination due to enlargement of the prostate gland ▶

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Drug Facts (continued)

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away at 1-800-222-1222.

Directions ■ take only one dose per day (24 hours) ■ only use dose cup provided	
adults & children 12 yrs & over	30 mL at bed time if needed or as directed by a doctor
children under 12 yrs	do not use

Other information ■ each 30 mL dose cup contains: potassium 5 mg; 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

Questions or comments? 1-866-467-2748

STOP PEELING HERE

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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:59779-893-06	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/22/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	09/22/2015	

