## 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.

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## CVS Health™ Nighttime Sleep-Aid Diphenhydramine HCl Alcohol Free Dye-Free Berry Flavor 12 FL OZ (354 mL)

**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

### 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

## **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.

**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)
- Measure with dosing cup provided

adults & children 12 yrs & over	One Dose = 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 contains: sodium 23 mg
- store at room temperature
- protect from light. Does not meet USP requirements for light-resistant packaging

## **Inactive ingredients**

anhydrous citric acid, flavor, glycerin, potassium citrate, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum.

#### Questions or comments?

1-866-467-2748

#### PRINCIPAL DISPLAY PANEL

CVS Health<sub>TM</sub>

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

NDC 69842-753-12

Alcohol Free

Nighttime

Sleep-Aid

Diphenhydramine HCl, 50 mg

Non – habit forming

**DYE FREE** 

**BERRY FLAVOR** 

12 FL OZ (354 mL)

SEE NEW WARNINGS.

## 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™

Nighttime Sleep-Aid.

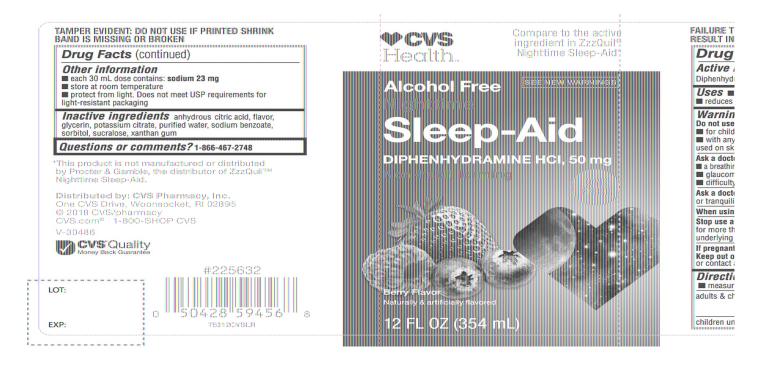
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### CVS HEALTH NIGHTTIME SLEEP AID

diphenhydramine hydrochloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-753
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<b>DIPHENHYDRAMINE HYDRO CHLO RIDE</b> (UNII: TC2D6 JAD40) (DIPHENHYDRAMINE - UNII:8 GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	50 mg in 30 mL	

Inactive Ingredients			
Ingredient Name	Strength		
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)			
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		Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:69842-753- 12	354 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/11/2017	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	10/11/2017	

## Labeler - CVS Pharmacy,Inc. (062312574)

Revised: 10/2017 CVS Pharmacy,Inc.