

## **EZ NITE SLEEP- diphenhydramine hydrochloride solution**

### **Kroger Company**

*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.*

-----

### **Kroger Co. EZ Nite Sleep 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 2 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 (1-800-222-1222).

**Directions**

- take only one dose per day (24 hours)
- only use the 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 contains:** sodium 20 mg
- store at 20-25°C (68-77°F)

**Inactive ingredients**

alcohol, anhydrous citric acid, FD&C blue #1, FD&C red #40, flavor, high fructose corn syrup, poloxamer 407, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium citrate

**Questions?**

**1-800-632-6900**

**Package/Label Principal Display Panel**

COMPARE TO the active ingredient of VICKS® ZZZQUIL® See back panel

Kroger®

Nighttime Sleep-Aid

EZ Nite Sleep

Diphenhydramine HCl 50mg per 30mL

Helps You Fall Asleep

OUR PHARMACIST RECOMMENDED

Not for Treating Cold or Flu

Non-Habit Forming

ALCOHOL 10%

Berry Flavor

12 FL OZ (354 mL)

COMPARE TO the active ingredient of VICKS® ZZZQUIL®  
\*See back panel

NDC 30142-549-40

 

**Nighttime Sleep-Aid**

**EZ Nite Sleep**

Diphenhydramine HCl  
50mg per 30mL

Helps You Fall Asleep

 Not for Treating Cold or Flu  
Non-Habit Forming

ALCOHOL 10%  
Berry Flavor

12 FL OZ (354 mL)

18640 45 F2

DISTRIBUTED BY  
THE KROGER CO.  
CINCINNATI, OHIO 45202  
QUALITY GUARANTEE  
www.kroger.com

DO NOT USE IF PRINTED  
NECKBAND IS BROKEN OR MISSING

0 41260 01709 4

**Drug Facts**

Active ingredient (in each 30 mL)	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

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

**When using this product**

- avoid alcoholic beverages

PEEL BACK FOR DRUG FACTS

18640 45 B1

**Drug Facts (continued)**

**Stop use and ask a doctor if** sleeplessness persists continuously for more than 2 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 (1-800-222-1222).

**Directions**

- take only one dose per day (24 hours)
- only use the 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 contains: sodium 20 mg
- store at 20-25°C (68-77°F)

**Inactive ingredients** alcohol, anhydrous citric acid, FD&C blue #1, FD&C red #40, flavor, high fructose corn syrup, poloxamer 407, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium citrate

**Questions?** 1-800-632-6900

\*This product is not manufactured or distributed by Procter & Gamble. Vicks® and ZzzQuil® are registered trademarks of The Procter & Gamble Company.

ADHESIVE AREA  
NO COATING • NO VARNISH • NO TYPE

## EZ NITE SLEEP

diphenhydramine hydrochloride solution

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30142-549
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII: 8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	50 mg in 30 mL

Inactive Ingredients	
Ingredient Name	Strength
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>HIGH FRUCTOSE CORN SYRUP</b> (UNII: XY6UN3QB6S)	
<b>POLOXAMER 407</b> (UNII: TUF2IVW3M2)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SODIUM CITRATE, UNSPECIFIED FORM</b> (UNII: 1Q73Q2JULR)	

Product Characteristics			
<b>Color</b>	PURPLE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	BERRY	<b>Imprint Code</b>	
<b>Contains</b>			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30142-549-30	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/09/2019	
2	NDC:30142-549-40	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/09/2019	
3	NDC:30142-549-50	2 in 1 PACKAGE	05/09/2019	
3		355 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	05/09/2019	

**Labeler** - Kroger Company (006999528)

