

NIGHTTIME SLEEP-AID - diphenhydramine hcl liquid
Guardian Drug Company

Guardian Nighttime Sleep-aid-633

ACTIVE INGREDIENT(S)

Diphenhydramine HCl 50 mg

PURPOSE

Nighttime sleep-aid

USE(S)

- for relief of occasional sleeplessness
- helps you to fall asleep if you have difficulty falling asleep

WARNINGS

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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 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 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

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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.

DIRECTIONS

- take only one dose per day (24 hours) - see Overdose warning
- only use dosage cup that is included with this product for accurate dosing
- mL = millilitere; Tbsp = teblespoons

Age	Dose
adults & chlidren 12 year & over	one = 30 mL (2Tbsp) at bedtime if needed or as directed by a doctor
childrens under 12 years	do not use

OTHER INFORMATION

- each 30 mL (2 Tbsp) contain: sodium 30 mg
- store at room temperature
- protect from light

INACTIVE INGREDIENTS

citric acid, FD&C Blue # 1, FD&C Red # 40, flavors, high fructose corn syrup, polyoxyl 40 stearate, purified water, saccharine sodium, sodium benzoate, sodium citrate.

PRINCIPAL DISPLAY PANEL

NDC 53041-633-58

*Compare to the active ingredient in **ZZZQUIL**[®] Nighttime Sleep-Aid

Nighttime Sleep-Aid

Warming Berry Flavor

Relieves:

Occasional Sleeplessness

6 FL OZ (177 ML)

<p>Drug Facts</p> <p>Active ingredient (in each 30 mL) Purpose Diphenhydramine HCl 50 mgNighttime sleep-aid</p> <p>Uses</p> <ul style="list-style-type: none"> for relief of occasional sleeplessness helps you to fall asleep if you have difficulty falling asleep <p>Warnings</p> <p>Do not use</p> <ul style="list-style-type: none"> 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 	<p style="text-align: right;">NDC 53041-633-58 *Compare to the active ingredient in ZzzQuil® Nighttime Sleep-Aid</p>  <p style="text-align: center;">Nighttime Sleep-Aid</p> <p style="text-align: center;">Warming Berry Flavor</p> <p style="text-align: center;">Relieves:</p> <ul style="list-style-type: none"> Occasional Sleeplessness <p style="text-align: center;">6 FLOZ (177 ML)</p>	<p><small>*This product is not manufactured or distributed by Procter & Gamble, Inc., the distributor of ZzzQuil® Nighttime Sleep-Aid Liquid.</small></p> <p>Guardian Drug Company 2 Charles Court Dayton, NJ 08810</p> <p>MFR# 53041 REV 0124</p>  <p>0 53041 63358 4</p> <p>TAMPER EVIDENT: Do not use if imprinted shrinkband is missing or broken.</p> <p style="text-align: center;">UNVARNISHED ARFA FOR LOT & EXP. 1/2" x 1 1/4"</p>
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← **PEEL HERE FOR CONTINUED DRUG FACTS**

<p>GLUE AREA</p>	<p>Drug Facts (continued)</p> <table border="1" style="width: 100%;"> <thead> <tr> <th>Age</th> <th>Dose</th> </tr> </thead> <tbody> <tr> <td>adults & children 12 years & over</td> <td>one dose = 30 mL (2 Tbsp) at bedtime if needed or as directed by a doctor</td> </tr> <tr> <td>children under 12 years</td> <td>do not use</td> </tr> </tbody> </table> <p>Other information</p> <ul style="list-style-type: none"> each 30 mL (2 Tbsp) contains: sodium 30 mg store at room temperature protect from light <p>Inactive ingredients citric acid, FD&C Blue # 1, FD&C Red # 40, flavors, high fructose corn syrup, polyoxyl 40 stearate, purified water, saccharin sodium, sodium benzoate, sodium citrate.</p> <p style="text-align: center;"><small>Failure to follow these warnings could result in serious consequences.</small></p>	Age	Dose	adults & children 12 years & over	one dose = 30 mL (2 Tbsp) at bedtime if needed or as directed by a doctor	children under 12 years	do not use
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PEEL BACK PORTION OF LABEL

<p>Drug Facts (continued)</p> <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> a breathing problem such as emphysema, or chronic bronchitis glaucoma difficulty in urination due to enlargement of the prostatic gland heart disease <p>Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers or any other sleep-aid.</p> <p>When using this product</p> <ul style="list-style-type: none"> avoid alcoholic beverages and other drugs that cause drowsiness drowsiness will occur be careful when driving a motor vehicle or operating machinery → 	<p>Drug Facts (continued)</p> <p>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.</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children.</p> <p>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.</p> <p>Directions</p> <ul style="list-style-type: none"> take only one dose per day (24 hours) - see Overdose warning only use dosage cup that is included with this product for accurate dosing mL = milliliter; Tbsp = tablespoons → 	<p>GLUE AREA</p>
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NIGHTTIME SLEEP-AID

diphenhydramine hcl liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53041-633
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	50 mg in 30 mL
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Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
POLYOXYL 40 STEARATE (UNII: 13A4J4NH9I)	
SACCHARIN SODIUM ANHYDROUS (UNII: I4807BK602)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	

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:53041-633-58	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/11/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	part338	01/11/2024	

Labeler - Guardian Drug Company (119210276)

Establishment

Name	Address	ID/FEI	Business Operations
Guardian Drug Company		119210276	MANUFACTURE(53041-633)