

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

.

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

.

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)

Drug Facts

Active ingredient (in each 30 mL) **Purpose**
Diphenhydramine HCl 50 mgNighttime sleep-aid

Uses

- for relief of occasional sleeplessness
- helps you 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

← **PEEL HERE FOR CONTINUED DRUG FACTS**



GUARDIAN®

Nighttime Sleep-Aid

Warming Berry Flavor

Relieves:

- Occasional Sleeplessness

6 FLOZ (177 ML)

*This product is not manufactured or distributed by Procter & Gamble, Inc., the distributor of ZzzQuil® Nighttime Sleep-Aid Liquid.

Guardian Drug Company
2 Charles Court
Dayton, NJ 08810

MFR# 53041 REV 0124



0 53041 63358 4

TAMPER EVIDENT:
Do not use if imprinted shrinkband is missing or broken.

UNVARNISHED AREA FOR LOT & EXP.
1/2" x 1 1/4"

GLUE AREA

Drug Facts (continued)

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

Other information

- each 30 mL (2 Tbsp) contains: 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, saccharin sodium, sodium benzoate, sodium citrate.

Failure to follow these warnings could result in serious consequences.

PEEL BACK PORTION OF LABEL

Drug Facts (continued)

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 →

Drug Facts (continued)

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.

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 = milliliter; Tbsp = tablespoons →

GLUE AREA

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
-----------------	-------------------	----------

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)	
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)