

NIGHTTIME SLEEP AID BERRY FLAVOR- diphenhydramine hydrochloride liquid **Raritan Pharmaceuticals 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.

DRx CHOICE® 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

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.

Overdose warning:

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 cup provided

adults & children 12yrs & 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:** 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.

PRINCIPAL DISPLAY PANEL

DRx CHOICE®

NDC 68163-730-06

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

Sleep-Aid

Nighttime

Diphenhydramine HCl

Non-Habit Forming

BERRY FLAVOR

Naturally and Artificially Flavored

Not for treating Cold or Flu See Warnings

6 FL OZ (177 mL)

\$1.99 AMAZING NEW VALUE!

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.

Manufactured by:

Raritan Pharmaceuticals

8 Joanna Court,

East Brunswick, NJ 08816

Failure to follow these warnings could result in serious consequences.

Drug Facts

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Diphenhydramine HCl 50 mg.....	Nighttime sleep-aid

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■ a breathing problem such as emphysema, or chronic bronchitis
■ glaucoma
■ difficulty in urination due to enlargement of the prostate gland ▶

TAMPER EVIDENT: Do not use if printed shrink band is missing or broken

PEEL BACK FOR DRUG FACTS

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.

Manufactured by:
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8 Joanna Court,
East Brunswick, NJ 08816

LOT: 73006DC99LR
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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) ■ 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, FD&C Blue #1, FD&C Red #40, flavor, glycerin, potassium citrate, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum

Questions or comments? 1-866-467-2748

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STOP PEELING HERE

NIGHTTIME SLEEP AID BERRY FLAVOR

diphenhydramine hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68163-730
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)	
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 (Naturally and Artificially)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68163-730-06	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/17/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	04/17/2019	

Labeler - Raritan Pharmaceuticals Inc (127602287)

Revised: 9/2023

Raritan Pharmaceuticals Inc