

SLEEP AID NIGHTTIME- diphenhydramine hcl liquid
P & L Development, LLC

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

- in 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
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizer.

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 a 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 (1-800-222-

1222) right away.

Directions

- take only one dose per day (24 hours)
- mL=milliliter
- keep dosing cup with product
- measure only with dosing cup provided. Do not use any other dosing device.
- adults and children 12 years and over
 - one dose=30 mL at bedtime if needed, or as directed by a doctor
- children under 12 years: do not use

Other information

- **each 30 mL contains:** sodium 23 mg
- store between 20-25°C (68-77°F). Do not refrigerate.
- protect from light

Inactive ingredients

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

Questions or comments?

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

Principal Display Panel

Compare to the active ingredient in ZzzQuil®*

ez nite

sleep aid

diphenhydramine HCl 50 mg

nighttime sleep-aid

- not for treating cold or flu
- alcohol 10%

berry flavor

fl oz (mL)

Failure to follow these warnings could result in serious consequences.

*This product is not manufactured or distributed by The Procter & Gamble Company. ZzzQuil® is a registered trademark of The Procter & Gamble Company.

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL AROUND DOSAGE CUP OR UNDER CAP IS BROKEN OR MISSING.

Manufactured by:

PL Developments

11865 S. Alameda St

Lynwood, CA 90262

Package Label

Failure to follow these warnings could result in serious consequences.

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Compare to the active ingredient in ZZZQUIL®
NDC 49580-0314-4

\$125

ez nite sleep aid

diphenhydramine HCl 50 mg
nighttime sleep-aid

4 fl oz (118 mL) berry flavor



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 2 weeks. Insomnia may be a symptom of a serious underlying medical illness.

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL AROUND BOTTLE OR UNDER CAP IS BROKEN OR MISSING.



Manufactured by:
PL Developments
11865 S. Alameda St
Lynwood, CA 90262

PLD-C262E
LB010366



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Drug Facts (continued under label) **PEEL HERE** →

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 (1-800-222-1222) right away.
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READYinCASE Nighttime Sleep Aid Berry Flavor

SLEEP AID NIGHTTIME

diphenhydramine hcl liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49580-0314
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)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYOXYL 40 STEARATE TYPE I (UNII: 13A4J4NH9I)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SODIUM ANHYDROUS (UNII: I4807BK602)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
ALCOHOL (UNII: 3K9958V90M)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49580-0314-6	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/31/2016	
2	NDC:49580-0314-2	355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/31/2016	
3	NDC:49580-0314-4	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/31/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M010	08/31/2016	

Labeler - P & L Development, LLC (101896231)