

EZ NITE SLEEP- diphenhydramine hcl liquid
Safeway, 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.

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

- with any other product containing diphenhydramine, even one used on skin
- for children under 12 years of age
- with other drugs that cause drowsiness such as antihistamines, nighttime cold/flu products, and other nighttime sleep-aids

Ask a doctor before use if you have

- breathing problem such as asthma emphysema or chronic bronchitis
- glaucoma
- heart disease
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers or any other sleep-aid.

When using this product

- drowsiness will occur
- avoid alcoholic beverages and other drugs that cause drowsiness
- be careful when driving a motor vehicle or operating machinery

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.

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 (1800-222-1222).

Directions

- take only one dose per day (24 hours) - (see overdose warning)
- mL=milliliter
- measure only with dosing cup provided. Do not use any other dosing device
- keep dosing cup with product
- adults and children 12 years and over
 - one dose=30mL 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 at 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, citrate dihydrate

Questions or comments?

Call 1-888-723-3929 Monday-Friday 7AM-6PM PST

Principal Display Panel

COMPARE TO ZZZQUIL® active ingredient*

Nighttime Sleep Aid

Diphenhydramine HCl 50 mg

- Non-Habit Forming
- Not for treating cold or flu

- 10 % alcohol
- See warnings

Berry Flavor

fl oz (mL)

Failure to follow these warnings could result in serious consequences.

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

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

DISTRIBUTED BY

BETTER LIVING BRANDS LLC

P.O. BOX 99, PLEASANTON, CA 94566-0009

www.betterlivingbrandsLLC.com

Package Label

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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 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.

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
■ Use only one dose per day (24 hours)
■ 18+ = 1 tablet ■ 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, polyvinyl 40 stearate, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium citrate

Questions or comments? Call 1-877-753-3005 Monday-Friday 9AM-5PM EST

SIGNATURE CARE NightTime Sleep Aid Berry Flavor

EZ NITE SLEEP

diphenhydramine hcl liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-014
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 (UNII: 13A4J4NH9I)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SODIUM ANHYDROUS (UNII: I4807BK602)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
ALCOHOL (UNII: 3K9958V90M)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-014-12	355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/30/2015	
2	NDC:21130-014-24	2 in 1 PACKAGE, COMBINATION	06/30/2015	
2		355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:21130-014-06	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/30/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/30/2015	

Labeler - Safeway, Inc. (009137209)