

GOOD SENSE SLEEP TIME- diphenhydramine hcl solution

L. Perrigo Company

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.

Perrigo Sleep Time Drug Facts

Active ingredient (in each 30 mL dose cup)

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
- with other drugs that cause drowsiness such as antihistamines and nighttime cold/flu products
- with other Nighttime products

Ask a doctor before use if you have

- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- difficulty in urination due to an 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
- drowsiness will occur
- do not drive a motor vehicle or operate 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. (1-800-222-1222)

Directions

- take only one dose per day (24 hours) – see Overdose warning
- use dose cup

adults & children 12 yrs & over	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 cup contains: sodium 20 mg
- store at 20-25°C (68-77°F)
- protect from light. Does not meet USP <671>.

Inactive ingredients

alcohol, anhydrous citric acid, FD&C blue #1, FD&C red #40, flavor, high fructose corn syrup, poloxamer 407, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium citrate

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

Non-Habit Forming

SleepTime

Nighttime Sleep-Aid

Diphenhydramine HCl

50 mg per 30 mL

Not For Treating Cold or Flu

See Warnings

Berry Flavor

DOCTOR RECOMMENDED #1 sleep-aid active ingredient

Compare to active ingredient of Vicks® ZzzQuil®

12 FL OZ (355 mL)

ALCOHOL 10%

Drug Facts (continued)

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Gluten Free *In the U.S. Source: Symphony Health Solutions.

Distributed By
Perrigo®
Allegan, MI 49010



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GOODSENSE® NDC 0113-0186-40

Non-Habit Forming

SleepTime

Nighttime Sleep-Aid Diphenhydramine HCl 50 mg per 30 mL

Not For Treating Cold or Flu
See Warnings

Berry Flavor

DOCTOR RECOMMENDS #1 sleep-aid active ingredient*

Compare to active ingredient of Vicks® ZzzQuil®

100% SATISFACTION GUARANTEED

12 FL OZ (355 mL) ALCOHOL 10%

DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING

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18640 C2 F2

GOOD SENSE SLEEP TIME

diphenhydramine hcl solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0 113-0 186
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
ALCOHOL (UNII: 3K9958V90M)	
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)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
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:0113-0186-30	177 mL in 1 BOTTLE		
2	NDC:0113-0186-40	355 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part338	07/02/2013	

Labeler - L. Perrigo Company (006013346)

Revised: 10/2014

L. Perrigo Company