

GOOD SENSE SLEEP TIME- diphenhydramine hcl capsule, liquid filled

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 softgel)

Diphenhydramine HCl 25 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 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

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.

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)

adults & children 12 yrs & over	2 softgels at bedtime if needed or as directed by a doctor
children under 12 yrs	do not use

Other information

- store at 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F)
- protect from light

Inactive ingredients

edible ink, FD&C blue #1, FD&C red #40, gelatin, glycerin, polyethylene glycol, purified water, sorbitol sorbitan solution

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

Non-Habit Forming

Sleep Time

Nighttime Sleep-Aid

Actual Size

Diphenhydramine HCl 25 mg

Not For Treating Cold or Flu

See Warnings

Compare to active ingredient of Vicks[®] ZzzQuil[®] LiquiCaps[®]

100% SATISFACTION GUARANTEED

12 Softgels

Drug Facts (continued)

Other information

- store at 20-25 °C (68-77 °F)
- avoid excessive heat do not store above 40 °C (104 °F)
- protect from light

Drug Facts (continued)

Inactive ingredients sedative, FD&C blue #1, FD&C red #40, glycerin, polyethylene glycol, purified water, sorbitol sorbitan solution

Questions or comments? 1-800-71-99260

Drug Facts

Active ingredient (in each softgel) Diphenhydramine HCl 25mg

Purpose 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
 - 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 2 weeks, however, some may be a symptom of serious underlying medical illness.
- If pregnant or breastfeeding, ask a health professional before use.

Directions

- Take only one dose per day (24 hours)
- Adults & children 12 yrs & over: 2 softgels at bedtime if needed or as directed by a doctor
- Children under 12 yrs: do not use

Distributed by **Perrigo**® Allegen, MI 49010

DO NOT USE IF BUSTER UNITS BROKEN OR TORN
Gluten Free

05253 C2 C3



◆ Of U.S. physicians surveyed by an independent market research firm.



GOODSENSE®
NDC 0113-0052-53

Non-Habit Forming

Sleep Time

Nighttime Sleep-Aid

Diphenhydramine HCl 25 mg

Not For Treating Cold or Flu
See Warnings

Compare to active ingredient of
Vicks® ZzzQuil® LiquiCaps®

100% SATISFACTION GUARANTEED

12 Softgels

Actual Size

GOOD SENSE SLEEP TIME
diphenhydramine hcl capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0113-0052
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	

Product Characteristics

Color	PURPLE	Score	no score
Shape	OVAL	Size	15mm
Flavor		Imprint Code	052
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0113-0052-53	6 in 1 CARTON	02/06/2014	
1		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0113-0052-62	12 in 1 CARTON	02/06/2014	
2		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:0113-0052-67	24 in 1 CARTON	05/13/2019	
3		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part338	02/06/2014	

Labeler - L. Perrigo Company (006013346)

