# 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.

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### **Perrigo Sleep Time Drug Facts**

## Active ingredient (in each 30 mL)

Diphenhydramine HCI 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 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)
- only use the dose cup provided

adults & children	30 mL at bed time if needed
12 yrs & over	or as directed by a doctor
children under 12 yrs	do not use

#### Other information

- each 30 mL contains: sodium 20 mg
- store at 20-25°C (68-77°F)

## **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?

1-800-719-9260

## Package/Label Principal Display Panel

GOODSENSE<sub>®</sub>

Non-Habit Forming

Sleep Time

Nighttime Sleep-Aid

Diphenhydramine HCl 50 mg per 30 mL

Not For Treating Cold or Flu

#1 DOCTOR RECOMMENDED sleep-aid active ingredient

Berry Flavor

Compare to active ingredient of Vicks® ZzzQuil®

**ALCOHOL 10%** 





## Drug Facts (continued) Stop use and ask a doctor if

Stop use and ask a doctor if seleeplessness 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).

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#### Directions

12 yrs

■ take only one dose per day (24 hours)
■ only use the dose cup provided

adults & children 12 yrs & over 30 mL at bed time if needed or as directed by a doctor

#### Other information

■ each 30 mL contains: sodium 20 mg
■ store at 20-25°C (68-77°F)

do not use

Inactive ingredients almost

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Questions?1-800-719-9260

#### **GOOD SENSE SLEEP TIME**

diphenhydramine hcl solution

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:0113-0186

Route of Administration ORAL

## **Active Ingredient/Active Moiety**

Ingredient Name

Basis of Strength

DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40)

(DIPHENHYDRAMINE - UNII:8GTS82S83M)

DIPHENHYDRAMINE

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, UNSPECIFIED FORM (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; Type 0: Not a Combination Product	07/02/2013		
2	NDC:0113-0186- 40	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/02/2013		

Marketing In	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: 8/2022 L. Perrigo Company