# GOOD SENSE NIGHTTIME SLEEP AID- diphenhydramine hydrochloride tablet, film coated

#### 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 Nighttime Sleep Aid Drug Facts**

#### **Active ingredient (in each caplet)**

Diphenhydramine HCl 25 mg

#### **Purpose**

Nighttime sleep-aid

#### Use

for relief of occasional sleeplessness

### 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 drinks
- drowsiness may 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:

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

#### **Directions**

adults and children 12 years and over	take 2 caplets at bedtime if needed, or as
	directed by a doctor
children under 12 years	do not use

#### Other information

- each caplet contains: calcium 15 mg
- store at 20-25°C (68-77°F). Avoid high humidity. Protect from light.
- · do not use if printed seal under cap is broken or missing

### **Inactive ingredients**

carnauba wax, crospovidone, dibasic calcium phosphate dihydrate, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, pregelatinized starch, stearic acid, titanium dioxide

#### Questions or comments?

1-800-719-9260

## **Principal Display Panel**

**GOODSENSE**<sub>®</sub>

Pain Reliever Free

Nighttime Sleep Aid

Diphenhydramine HCI 25 mg

Helps You Fall Asleep
 Non-Habit Forming

**Actual Size** 

100 Caplets

Compare to active ingredient of Simply Sleep® Nighttime Sleep Aid Caplets



: #3758 C5 C3

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EXP.

LOT NO.



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#### **GOOD SENSE NIGHTTIME SLEEP AID**

diphenhydramine hydrochloride tablet, film coated

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:0113-0431

Route of Administration ORAL

### **Active Ingredient/Active Moiety**

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

Ingredient Name

CARNAUBA WAX (UNII: R12CBM0EIZ)

CROSPOVIDONE (15 MPA.S AT 5%) (UNII: 68401960MK)

DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)

FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

FD&C BLUE NO. 2 (UNII: L06K8R7DQK)

HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)

MAGNESIUM STEARATE (UNII: 70097M6I30)

MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)

POLYSORBATE 80 (UNII: 6OZP39ZG8H)

STEARIC ACID (UNII: 4ELV7Z65AP)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Product Characteristics			
Color	BLUE (Light Blue)	Score	no score
Shape	OVAL	Size	11mm
Flavor		Imprint Code	L431
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0113-0431- 62	12 in 1 CARTON	04/25/2001	
1		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		

2	NDC:0113-0431- 68	18 in 1 CARTON	05/21/2019	12/31/2021
2		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:0113-0431- 78	1 in 1 CARTON	12/29/2021	
3		100 in 1 BOTTLE; 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	04/25/2001	

## Labeler - L. Perrigo Company (006013346)

Revised: 12/2021 L. Perrigo Company