

NIGHTTIME SLEEP AID- diphenhydramine hcl 25 mg tablet, coated
Health Pharma USA LLC

NIGHTTIME SLEEP AID-Diphenhydramine HCl 25 mg

Active ingredient (in each caplet)

Diphenhydramine HCl 25 mg

Purpose

Nighttime sleep-aid

Uses

- relief of occasional sleeplessness

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

Ask a doctor before use if you have

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

Ask your doctor or pharmacist before use if you are

- taking sedative or tranquilizers or any other sleep-aid

When using this product

- drowsiness will occur
- avoid alcoholic beverages and other drugs that cause drowsiness
- excitability may occur, especially in children
- alcohol, sedatives and tranquilizers may increase 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 a 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 (1-800-222-1222) right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- **do not take more than directed(see overdose warning)**
- **adults and children 12 years of age and over:-** take 2 caplets at bedtime if needed or as directed by a doctor
- **children under 12 years of age:**do not use

Other Information

- Each caplet contains: Calcium 23.52 mg
- store at controlled room temperature 25°C (77°F); excursions permitted between 15-30°C (59-86°F)
- read all product information before using
- TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Inactive Ingredients

Dicalcium Phosphate, Microcrystalline Cellulose, Croscarmellose Sodium, Stearic Acid, Colloidal Silicon Dioxide, Magnesium Stearate, Film Coat AMB Blue, Polyethylene Glycol, Polyvinyl Alcohol, Brilliant Blue Lake, Indigo Carmel Lake, Titanium dioxide, Talc

Questions or comments?

Call 1-844-832-1138

9AM – 5PM Monday-Friday

Principal Display Panel

Diphenhydramine HCl 25 mg/Nighttime sleep-aid

Compare to Tylenol® Simply Sleep active ingredients*

* This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Simply Sleep®.

300 CAPLETS easy to swallow
mint tablets

Health Pharma

Nighttime

Sleep-Aid

Diphenhydramine HCl 25 mg
Nighttime Sleep Aid

Compare to Tylenol® Simply Sleep active ingredients

NDC 71679-110-03

- Does Not Contain Pain Reliever
- Non-Habit Forming

Drug Facts

Active ingredient (in each caplet)	Purpose
Diphenhydramine HCl 25mg	Nighttime sleep-aid

Uses: ■ relief of occasional sleeplessness

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DRUG FACTS CONTINUED on back of the label ▶

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING


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Mfg / Dist by:
Health Pharma
Rahway, NJ 07065
www.health-pharma.us



3 71679 11003 2

Lot No.:
Exp. Date:



MADE IN THE USA

Drug Facts (Continued)

- 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 a 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 (1-800-222-1222) right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms

Directions

- Each caplet contains: Calcium 23.52 mg
- store at 25°C (77°F); excursions permitted between 150-30°C (59°-86°F)
- read all product information before using

Other information

- Each caplet contains: Calcium 23.52 mg
- store at controlled room temperature 25°C (77°F) excursions permitted between 15-30°C (59-86°F)
- read all product information before using

Inactive ingredients: May Contain:
dicalcium phosphate, microcrystalline cellulose, croscarmellose sodium, stearic acid, colloidal silicon dioxide, magnesium stearate, film coat AMB blue, polyethylene glycol, polyvinyl alcohol, brilliant blue lake, indigo carmel lake, titanium dioxide, talc

**Questions or comments? Call 1-844-832-1138
9AM - 5PM Monday - Friday**

NDC 71679-110-10

NIGHTTIME SLEEP AID
diphenhydramine hcl 25 mg tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71679-110
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
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	blue	Score	no score
Shape	CAPSULE	Size	11mm
Flavor		Imprint Code	S25
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71679-110-03	300 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2022	
2	NDC:71679-110-06	600 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2022	
3	NDC:71679-110-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M010	01/01/2022	

Labeler - Health Pharma USA LLC (080804485)

Establishment

Name	Address	ID/FEI	Business Operations
Health Pharma USA LLC		080804485	manufacture(71679-110)

Revised: 10/2023

Health Pharma USA LLC