

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

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.

Sleep Aid - Diphenhydramine HCL, 25mg Tablets

Active ingredient (in each caplet)

Diphenhydramine HCl 25 mg

Purpose

Nighttime sleep-aid

Uses

provides 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 emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland
- glaucoma
- heart disease

Ask a 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 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

Colloidal silicon dioxide, Croscarmellose sodium, Dicalcium phosphate, FD&C Blue #1, FD&C Blue #2, Magnesium stearate, Microcrystalline cellulose, Polyethylene glycol, Polyvinyl alcohol, Talc, Titanium dioxide

Questions or comments?

Call toll free 1-844-832-1138 Monday through Friday 9AM – 5PM EST

Principal Display Panel**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®.

Diphenhydramine HCl Tablets, 25 mg



Health Pharma USA LLC

1600 Hart Street, Rahway, NJ 07065
Phone: 732-540-8421

BULK LABEL _____ of _____

PRODUCT NAME: Diphenhydramine HCl 25 mg Caplets (Blue)

PRODUCT CODE # PC084

LOT #

Labeler code – 71679-084-00

NET WEIGHT (KG)

Caplets/BOX

18.00

70,000

WARNING: Keep out of Children. This bulk shipment is intended for further processing only. Repackage contents as soon as possible. This is a shipping container only and will not protect contents from damage by heat, cold and moisture indefinitely. Manufacturer will not accept responsibility for spoilage or violations of the food, Drug and cosmetic act due to prolonged storage in this container. Contents must be repackaged prior to resale and must be labeled in full compliance with the requirement of the Food, Drug and Cosmetic Act.

STORAGE: Store at a controlled room temperature 15-30°C (59-86° F)

NIGHTTIME SLEEP AID

diphenhydramine hcl 25 mg tablet, coated

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:71679-084

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
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
SILICON DIO XIDE (UNII: ETJ7Z6XBU4)	

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:71679-084-00	1 in 1 BOX	06/01/2017	
1		70000 in 1 BAG; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/01/2017	

Labeler - Health Pharma USA LLC (080804485)

Establishment

Name	Address	ID/FEI	Business Operations
Health Pharma USA LLC		080804485	manufacture(71679-084)

Revised: 11/2019

Health Pharma USA LLC