

**NIGHTTIME SLEEP AID- diphenhydramine hcl 25 mg tablet, coated**  
**HealthLife of USA**

*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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**Drug Facts**

**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 or [www.healthlifeofusa.com](http://www.healthlifeofusa.com)

**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



## NIGHTTIME SLEEP AID

diphenhydramine hcl 25 mg tablet, coated

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69517-110
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE 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 GLYCOLS (UNII: 3WJQ0SDW1A)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	

### Product Characteristics

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69517-110-25	25 in 1 BOX	06/01/2017	
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:69517-110-50	50 in 1 BOX	06/01/2017	
2		2 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:69517-110-02	2 in 1 POUCH	06/01/2017	
3		2 in 1 POUCH; Type 0: Not a Combination Product		
4	NDC:69517-110-01	1000 in 1 BOTTLE	06/01/2017	
4	NDC:69517-110-05	500 in 1 BOTTLE		
4	NDC:69517-110-30	30 in 1 BOTTLE		
4		1 in 1 CARTON; 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	

## Establishment

Name	Address	ID/FEI	Business Operations
Elysium Pharmaceutical Ltd.		915664486	manufacture(69517-110)

Revised: 6/2017

HealthLife of USA