

NIGHTTIME SLEEP AID- diphenhydramine hcl tablet, coated
HealthLife of USA LLC

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

Inactive Ingredients

Colloidal Silicon Dioxide, Croscarmellose Sodium, Dicalcium Phosphate, Magnesium Stearate, Microcrystalline Cellulose (PH-102), Titanium dioxide, Brilliant Blue FCF Aluminum lake (FD&C Blue No. 1), Indigo Carmel lake (FD&C Blue No. 2).

Questions or comments?

Call 1-844-832-1138

9AM – 5PM Monday - Friday

Principal Display Panel-300 Caplets

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 ■ Do not take more than directed (See overdose warning) ■ Adults and children 12 years 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 Inactive Ingredients: Colloidal silicon dioxide, Croscarmellose sodium, Dicalcium Phosphate, Magnesium stearate, Microcrystalline Cellulose (PH-102), Titanium dioxide, Brilliant Blue FCF Aluminum lake (FD&C Blue No.1), Indigo Carmine lake (FD&C Blue No.2). Questions or comments? Call 1-844-832-1138 9AM - 5PM Monday - Friday	
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NDC 69517-004-03

Compare to Tylenol® Simply Sleep active ingredients*

Nighttime Sleep-Aid

Diphenhydramine HCl 25 mg
Nighttime Sleep Aid

- Does Not Contain Pain Reliever
- Non-Habit Forming

300 CAPLETS

Drug Facts Active ingredient (in each caplet) Diphenhydramine HCl 25mg 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 ■ alcohol, sedatives and tranquilizers may increase drowsiness DRUG FACTS CONTINUED on back of the box TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING *This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Simply Sleep®. Distributed by: HealthLife® of USA, LLC Rahway, NJ 07065 www.healthlifeusa.com 3 69517 00403 2 PEEL HERE	
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Principal Display Panel-600 Caplets

NDC 69517-004-06

Compare to Tylenol® Simply Sleep active ingredients*

Nighttime Sleep-Aid

Diphenhydramine HCl 25 mg
Nighttime Sleep Aid

- Does Not Contain Pain Reliever
- Non-Habit Forming

600 CAPLETS

easy to swallow mini tablets

Drug Facts Active ingredient (in each caplet) Diphenhydramine HCl 25mg 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	Drug Facts (continued) 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	Drug Facts (continued) Directions ■ do not take more than directed (See overdose warning) ■ Adults and children 12 years 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 Inactive ingredients: Colloidal silicon dioxide, Croscarmellose sodium, Dicalcium Phosphate, Magnesium stearate, Microcrystalline Cellulose (PH-102), Titanium dioxide, Brilliant blue FCF Aluminum lake (FD&C Blue No.1), Indigo Carmine lake (FD&C Blue No.2). Questions or comments? Call 1-844-832-1138 9AM - 5PM Monday - Friday	TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING *This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Simply Sleep®. Distributed by: HealthLife® of USA, LLC Rahway, NJ 07065 www.healthlifeusa.com 3 69517 00406 3
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Principal Display Panel-1000 Caplets



NDC 69517-004-10

Compare to Tylenol® Simply Sleep active ingredients*

Nighttime Sleep-Aid

Diphenhydramine HCL
25 mg / Nighttime Sleep Aid

Does Not Contain Pain Reliever
Non-Habit Forming

1000 CAPLETS



Drug Facts

Active ingredient (in each caplet)
Diphenhydramine HCl 25mg

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 alcohol, beverages and other drugs that cause drowsiness ■ drowsiness 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 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, Magnesium stearate, Microcrystalline Cellulose (PH-102), Titanium dioxide, Brilliant blue FCF Aluminum lake (FD&C Blue No. 1), Indigo Carmine lake (FD&C Blue No. 2).
Questions or comments? Call toll free 1-844-832-1138 Monday through Friday 9AM - 5PM EST

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Distributed by:
HealthLife® of USA, LLC
Rahway, NJ 07065
www.healthlifeusa.com

NIGHTTIME SLEEP AID

diphenhydramine hcl tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69517-004
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)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

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:69517-004-03	300 in 1 BOTTLE; Type 0: Not a Combination Product	09/25/2025	
2	NDC:69517-004-06	600 in 1 BOTTLE; Type 0: Not a Combination Product	09/25/2025	
3	NDC:69517-004-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	09/25/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M010	09/25/2025	

Labeler - HealthLife of USA LLC (079656178)

Registrant - HealthLife of USA LLC (079656178)

Establishment

Name	Address	ID/FEI	Business Operations
ELYSIUM PHARMACEUTICALS LIMITED		863182240	manufacture(69517-004)

Establishment

Name	Address	ID/FEI	Business Operations
HHH PHARMA USA LLC		062788820	pack(69517-004)

Revised: 9/2025

HealthLife of USA LLC