

**MAXIMUM STRENGTH NIGHTTIME SLEEP-AID- diphenhydramine hcl capsule, liquid filled
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.

Maximum Strength Nighttime Sleep-Aid

Drug Facts

Maximum Strength Nighttime Sleep-Aid

Purpose

Nighttime Sleep-Aid

Active Ingredient (in each softgel)

Diphenhydramine HCL 50mg

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 antihistamine 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
- 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 1 softgel at bedtime if needed or as directed by a doctor
- **Children under 12 years of age:** Do not use

Other Information

- Store at 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

- FD&C Blue#1
- Gelatin
- Glycerin
- Polyethylene glycol
- Polyvinyl acetate phthalate
- Polyvinyl glycol
- Sorbitol
- Titanium Dioxide
- Water

Questions or Comments?

Call toll free 1-844-832-1138 Monday through Friday 9AM -5PM EST or www.healthlifeofusa.com

Maximum Strength Nighttime Sleep-Aid Diphenhydramine HCL 50mg / Nighttime Sleep-Aid

16 Softgels

afe & Non-Habit Forming

Get to sleep Fast

Sleep Soundly

Wake Refreshed

Compare to Unisom® Sleepgels® active ingredients

Distributed by:
 Healthlife of USA LLC
 Rahway
 NJ 07065
 www.healthlifeofusa.com

MAXIMUM STRENGTH NIGHTTIME SLEEP-AID

diphenhydramine hcl capsule, liquid filled



Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69517-117
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	50 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POLYVINYL ACETATE PHTHALATE (UNII: 58QVG85GW3)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	purple	Score	no score
Shape	OVAL	Size	13mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69517-117-16	1 in 1 CARTON	05/02/2017	
1		16 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	05/02/2017	

Labeler - Healthlife of USA (079656178)**Establishment**

Name	Address	ID/FEI	Business Operations
Healthlife of USA		079656178	repack(69517-117)

Establishment

Name	Address	ID/FEI	Business Operations
Elysium Pharmaceuticals Limited		915664486	manufacture(69517-117) , pack(69517-117)

Revised: 10/2017

Healthlife of USA