

## **NIGHT TIME SLEEP AID- diphenhydramine hcl capsule**

### **Hy-Vee**

*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 softgel)**

Diphenhydramine HCl 50 mg

#### **Purpose**

Nighttime sleep-aid

#### **Use**

for 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

##### **Ask a doctor before use if you have**

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

##### **Ask a doctor or pharmacist before use if you are**

taking sedatives or tranquilizers.

##### **When using this product**

avoid alcoholic drinks.

##### **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.**

In case of overdose, get medical help or contact a Poison Control Center right away.

##### **Directions**

- adults and children 12 years of age and over: 1 softgel (50 mg) at bedtime if needed, or as directed

by a doctor

**Other information**

- store at 15°-30°C (59°-86°F)

**Inactive ingredients**

edible white ink, FD&C blue #1, gelatin, glycerin, light mineral oil\*, polyethylene glycol, purified water, sorbitol-sorbitan

\*may contain this ingredient

**Questions or comments?**

Call toll free **1-800-289-8343 Monday-Friday 9AM-4PM CST**

**Principal Display Panel**

†Compare to the Active Ingredient of Unisom® SleepGels®

Maximum Strength

**Night Time Sleep Aid**

DIPHENHYDRAMINE HCl, 50 mg

Safe, Non-Habit Forming

- Fall Asleep Fast
- Sleep Soundly
- Wake up Refreshed

SOFTGELS\*\*

(\*\*LIQUID FILLED)

†This product is not manufactured or distributed by Chattem, Inc., owner of the registered trademark Unisom® SleepGels®.

DISTRIBUTED BY HY-VEE, INC.

5820 WESTOWN PARKWAY

WEST DES MOINES, IA 50266

[www.hy-vee.com](http://www.hy-vee.com)

**KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.  
TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN  
OR MISSING.**

**Package Label**

Hy-Vee health

Maximum Strength  
**Nighttime Sleep Aid**  
 Diphenhydramine HCl, 50 mg

Hy-Vee health

NDC 42507-236-32

†COMPARE TO  
 the Active Ingredient of  
 Unisom® SleepGels®

Maximum Strength  
**Nighttime Sleep Aid**  
 Diphenhydramine HCl, 50 mg



Actual Size

Safe, Non-Habit Forming



- Fall Asleep Fast
- Sleep Soundly
- Wake up Refreshed

**32 SOFTGELS\*\***  
 ONE SOFTGEL PER DOSE  
 (\*\*LIQUID FILLED)

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

PLD-227L  
 F0003035

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 5820 WESTOWN PARKWAY  
 WEST DES MOINES, IA 50266  
 SATISFACTION GUARANTEED  
 OR PURCHASE PRICE REFUNDED  
 FOR INFORMATION CALL  
 1-800-289-8343  
 www.hy-vee.com

\*This product is not manufactured or distributed by Chatham, Inc., owner of the registered trademark Unisom® SleepGels®.

<b>Drug Facts</b>
<b>Active ingredient (in each softgel)</b> Diphenhydramine HCl 50 mg. Nighttime sleep-aid
<b>Use</b> for relief of occasional sleeplessness.
<b>Warnings</b>
Do not use
■ for children under 12 years of age
■ with any other product containing diphenhydramine, even one used on skin
<b>Ask a doctor before use if you have</b>
■ a breathing problem such as emphysema or chronic bronchitis
■ glaucoma
■ trouble urinating due to an enlarged prostate gland
<b>Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers.</b>
<b>When using this product avoid alcoholic drinks.</b>
<b>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.</b>
<b>If pregnant or breast-feeding, ask a health professional before use.</b>
<b>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</b>
<b>Directions</b>
■ adults and children 12 years of age and over: 1 softgel (50 mg) at bedtime if needed, or as directed by a doctor
<b>Other information</b> ■ store at 15°-30°C (59°-86°F)
<b>Inactive ingredients</b> edible white ink, FD&C blue #1, gelatin, glycerin, light mineral oil, polyethylene glycol, purified water, sorbitol-sorbitan
*may contain this ingredient
<b>Questions or comments?</b> Call toll free 1-800-289-8343 Monday-Friday 9AM-4PM CST

Hy-Vee Health Maximum Strength NightTime Sleep Aid

<b>NIGHT TIME SLEEP AID</b>			
diphenhydramine hcl capsule			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:42507-236
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			



Ingredient Name		Basis of Strength	Strength	
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)		DIPHENHYDRAMINE HYDROCHLORIDE	50 mg	
<b>Inactive Ingredients</b>				
Ingredient Name			Strength	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)				
GELATIN (UNII: 2G86QN327L)				
GLYCERIN (UNII: PDC6A3C0OX)				
LIGHT MINERAL OIL (UNII: N6K5787QVP)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
WATER (UNII: 059QF0KO0R)				
SORBITAN (UNII: 6O92ICV9RU)				
SORBITOL (UNII: 506T60A25R)				
<b>Product Characteristics</b>				
Color	BLUE	Score	no score	
Shape	CAPSULE	Size	13mm	
Flavor		Imprint Code	P50;A99;S90	
Contains				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42507-236-32	1 in 1 BOX	02/01/2014	
1		32 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL	part341	02/01/2014		

**Labeler** - Hy-Vee (006925671)

Revised: 12/2019

Hy-Vee