

**SLEEP AID MAXIMUM STRENGTH- diphenhydramine hcl capsule**  
**P & L Development, 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.*

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**Drug Facts**

**Active ingredient (in each softgel)**

Diphenhydramine HCl 50 mg

**Purpose**

Nighttime sleep-aid

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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 (1-800-222-1222)

**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, polyethylene glycol, propylene glycol\*, purified water, sorbitol-sorbitan

\*contains one or more of these ingredients

**Questions or comments?**

Call **1-877-753-3935 Monday-Friday 9AM-5PM EST**

**Principal Display Panel**

Maximum Strength

Sleep-Aid

diphenhydramine HCl 50 mg

nighttime sleep-aid

safe, non-habit forming

softgels

One Softgel Per Dose

†Compare to the active ingredient in Unisom® SleepGels®

†This product is not manufactured or distributed by Chattem, Inc., distributor of Unisom® SleepGels®.

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

**KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.**

Distributed by: **PL Developments**

200 Hicks Street

Westbury, NY 11590

## Package Label

<p><b>Drug Facts</b></p> <p><b>Active ingredient (in each softgel)</b> Diphenhydramine HCl 50 mg <span style="float: right;"><b>Purpose</b> Nighttime sleep-aid</span></p> <p><b>Use</b> For relief of occasional sleeplessness.</p> <p><b>Warnings</b>  <b>Do not use</b> ■ in 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,</b> avoid alcoholic drinks.  <b>Stop use and ask a doctor</b> if sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of a serious underlying medical illness.  <b>If pregnant or breast-feeding,</b> ask a health professional before use.  <b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).</p> <p><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</p> <p><b>Other information</b> ■ store between 15-30°C (59-86°F)</p> <p><b>Inactive ingredients</b> edible white ink, FD&amp;C blue #1, gelatin, glycerin, polyethylene glycol, propylene glycol*, purified water, sorbitan*, sorbitol          *contains one or more of these ingredients</p> <p><b>Questions or comments?</b> Call 1-877-753-3935 Monday-Friday 9AM-5PM EST</p> <p><small>*This product is not manufactured or distributed by Chatten, Inc., distributor of Unisom® SleepGels®.</small></p>	<p><b>1 BOTTLE INSIDE</b></p>  <p>maximum strength <b>sleep-aid</b></p> <p>diphenhydramine HCl 50 mg nighttime sleep-aid</p> <p>64 softgels one softgel per dose</p>	 <p>maximum strength <b>sleep-aid</b></p> <p>diphenhydramine HCl 50 mg nighttime sleep-aid</p> <p>safe, non habit-forming</p> <p>64 softgels one softgel per dose</p> <p><small>*Compare to the active ingredient in Unisom® SleepGels®</small></p>
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**TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.** **1 BOTTLE INSIDE**

**KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.**




Actual Size

Distributed by: **PL Developments**  
200 Hicks Street, Westbury, NY 11590

PLD-8270  
FD005436

Lot No.:  
Exp. Date:



3 59726 23666 9

## WELLNESS BASICS Maximum Strength Sleep-Aid

### SLEEP AID MAXIMUM STRENGTH

diphenhydramine hcl capsule

#### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59726-635
<b>Route of Administration</b>	ORAL		

#### Active Ingredient/Active Moiety

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

#### Inactive Ingredients

Ingredient Name	Strength
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITAN</b> (UNII: 6O92ICV9RU)	
<b>SORBITOL</b> (UNII: 506T60A25R)	

Product Characteristics			
<b>Color</b>	blue	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	13mm
<b>Flavor</b>		<b>Imprint Code</b>	P50;A99;D50;AP018
<b>Contains</b>			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59726-635-64	1 in 1 CARTON	09/30/2018	12/27/2024
1		64 in 1 BOTTLE, PLASTIC; 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	09/30/2018	12/27/2024

**Labeler** - P & L Development, LLC (800014821)

Revised: 9/2022

P & L Development, LLC