

## **SLEEP AID NIGHTTIME- diphenhydramine hcl capsule EQUALINE (SuperValu)**

*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

#### **Uses**

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**

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

##### **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 older: 1 softgel (50 mg) at bedtime if needed, or as directed by a doctor

**Other information**

- store between 15-30°C (59-86°F)

**Inactive ingredients**

FD&C blue #1, gelatin, glycerin, polyethylene glycol, purified water, sorbitol, sorbitan, white ink

**Questions or comments?**

Call toll free **1-855-423-2630**

**Principal Display Panel**

Compare to Unisom® SleepGels® active ingredient\*\*

**maximum strength****Sleep-Aid softgels**

diphenhydramine HCl, 50 mg

(nighttime Sleep-Aid)

- Fall asleep fast
- sleep soundly and wake up refreshed
- non habit-forming

liquid filled

softgels

\*\*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 UNFI  
PROVIDENCE, RI 02908 USA**

**Product Label**

NDC 41163-860-96


compare to  
**Unisom® SleepGels®**  
active ingredient\*\*

**EQUALINE®**

maximum strength  
**sleep-aid softgels**  
diphenhydramine HCl, 50mg  
(nighttime sleep-aid)

- fall asleep fast
- sleep soundly and wake up refreshed
- non habit-forming

**96** liquid filled softgels  
one softgel per dose actual size




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

<b>Drug Facts</b>	<p><b>Active ingredient (in each softgel)</b> Diphenhydramine HCl 50 mg..... Nighttime sleep-aid</p> <p><b>Use</b> For relief of occasional sleeplessness.</p> <p><b>Warnings</b></p> <p><b>Do not use</b></p> <ul style="list-style-type: none"> <li>■ for children under 12 years of age</li> <li>■ with any other product containing diphenhydramine, even one used on skin</li> </ul> <p><b>Ask a doctor before use if you have</b></p> <ul style="list-style-type: none"> <li>■ a breathing problem such as emphysema or chronic bronchitis</li> <li>■ glaucoma</li> <li>■ trouble urinating due to an enlarged prostate gland</li> </ul>
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DISTRIBUTED BY UNFI  
PROVIDENCE, RI 02908 USA

Like it or let us make it right.  
**That's our quality promise.**  
855-423-2630



PLD-1633A  
LB007287  
Lot No.:  
Exp. Date:

**PEEL HERE** →

**Drug Facts (continued)**

**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 (1-800-222-1222), 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 between 15-30°C (59-86°F)

**Inactive ingredients** FD&C blue #1, gelatin, glycerin, polyethylene glycol, purified water, sorbitan, sorbitol, white ink

**Questions or comments?**  
Call toll free 1-855-423-2630

**EQUALINE Maximum Strength Sleep-Aid**

<b>SLEEP AID NIGHTTIME</b>		
diphenhydramine hcl capsule		
<b>Product Information</b>		
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b> NDC:41163-860
<b>Route of Administration</b>	ORAL	
<b>Active Ingredient/Active Moiety</b>		
<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
DIPHENHYDRAMINE HYDROCHLORIDE (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>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SORBITAN</b> (UNII: 6O92ICV9RU)	

## 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
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41163-860-96	96 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/27/2019	
2	NDC:41163-860-32	1 in 1 BOX	12/27/2019	
2		32 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	part338	12/27/2019	

**Labeler** - EQUALINE (SuperValu) (006961411)

Revised: 11/2022

EQUALINE (SuperValu)