

**NIGHTTIME SLEEP AID- diphenhydramine hcl tablet, film coated  
SUPERVALU INC.**

*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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**Equaline 44-367**

***Active ingredient (in each caplet)***

Diphenhydramine HCl 25 mg

***Purpose***

Nighttime sleep-aid

***Use***

for relief of occasional sleeplessness

***Warnings***

**Do not use**

- in 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**

- difficulty in urination due to enlargement of the prostate gland
- a breathing problem such as emphysema or chronic bronchitis
- glaucoma

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

taking sedatives or tranquilizers.

**When using this product**

- drowsiness will occur
- use caution when driving a motor vehicle or operating machinery
- avoid alcoholic beverages

**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***

- **do not take more than directed**
- adults and children 12 years and over: take 2 caplets at bedtime if needed or as directed by a doctor
- children under 12 years: do not use

#### ***Other information***

- **each caplet contains:** calcium 30 mg
- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- protect from moisture
- see end flap for expiration date and lot number

#### ***Inactive ingredients***

corn starch, dicalcium phosphate, FD&C blue #1 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, silica gel, stearic acid, talc, titanium dioxide

#### ***Questions or comments?***

**1-877-932-7948**

#### **Principal Display Panel**

**compare to**

**Simply Sleep<sup>®</sup>**

active ingredient\*

**NDC 41163-367-08**

**EQUALINE<sup>®</sup>**

nighttime

**sleep aid**

diphenhydramine HCl 25 mg

(nighttime sleep aid)

- *for a restful night's sleep*
- *does not contain pain reliever*
- *safe, non-habit forming*

actual size

**24** mini caplets

**TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING**

\*This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Simply Sleep<sup>®</sup>.

50844 REV0516B36708

**DISTRIBUTED BY SUPERVALU INC.**

**EDEN PRAIRIE, MN 55344 USA**

**100% Quality**

**GUARANTEED**

Like it or let us make it right.

That's our quality promise.

877-932-7948

supervalprivatebrands.com

**Drug Facts** KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

<b>Active ingredient (in each caplet)</b> Diphenhydramine HCl 25 mg . . . . .	<b>Purpose</b> Nighttime sleep-aid
<b>Use</b> for relief of occasional sleeplessness	
<b>Warnings</b> Do not use <ul style="list-style-type: none"> <li>in children under 12 years of age</li> <li>with any other product containing diphenhydramine, even one used on skin</li> </ul>	
<b>Ask a doctor before use if you have</b> <ul style="list-style-type: none"> <li>difficulty in urination due to enlargement of the prostate gland</li> <li>a breathing problem such as emphysema or chronic bronchitis</li> <li>glaucoma</li> </ul>	
<b>Ask a doctor or pharmacist before use if you are taking</b> sedatives or tranquilizers.	
<b>When using this product</b> <ul style="list-style-type: none"> <li>drowsiness will occur</li> <li>use caution when driving a motor vehicle or operating machinery</li> <li>avoid alcoholic beverages</li> </ul>	
<b>Stop use and ask a doctor if</b> 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 (1-800-222-1222) right away.	

**Drug Facts (continued)**

**Directions**

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**Questions or comments?** 1-877-932-7948

**DOES NOT CONTAIN GLUTEN**  
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REV0516B36708

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**24 mini caplets**

**nighttime sleep aid**

**EQUALINE®**

• for a restful night's sleep  
 • does not contain pain reliever  
 • safe, non-habit forming

diphenhydramine HCl 25mg (nighttime sleep aid)

**nighttime sleep aid**

**EQUALINE®**

compare to Simply Sleep® active ingredient\*  
NDC 41163-367-08

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TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING



Equaline 44-367

## NIGHTTIME SLEEP AID

diphenhydramine hcl tablet, film coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:41163-367
<b>Route of Administration</b>	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
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	BLUE	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	11mm
<b>Flavor</b>		<b>Imprint Code</b>	44;367
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41163-367-08	2 in 1 CARTON	06/10/2000	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:41163-367-06	1 in 1 CARTON	06/10/2000	
2		200 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:41163-367-12	1 in 1 CARTON	06/10/2000	
3		100 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	06/10/2000	

**Labeler** - SUPERVALU INC. (006961411)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(41163-367)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(41163-367)

Revised: 10/2016

SUPERVALU INC.