

**SLEEP-EZ NIGHTTIME SLEEP AID- diphenhydramine hcl 25 mg tablet, coated  
Safrel Pharmaceuticals, 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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**Sleep-EZ Nighttime Sleep Aid**

**Active ingredient (in each caplet)**

Diphenhydramine HCl 25 mg

**Purpose**

Nighttime sleep-aid

**Uses**

provides 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 antihistamines and nighttime cold/flu products

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

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

**Ask a 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
- excitability may occur, especially in children
- 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 of age and over:** - take 2 caplets at bedtime if needed or as directed by a doctor
- **children under 12 years of age:** do not use

### **Other Information**

- Each caplet contains: Calcium 23.52 mg
- store at 25°C (77°F); excursions permitted between 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**

Colloidal silicon dioxide, Croscarmellose sodium, Dicalcium phosphate, FD&C Blue #1, FD&C Blue #2, Magnesium stearate, Microcrystalline cellulose, Polyethylene glycol, Polyvinyl alcohol, Talc, Titanium dioxide

### **Questions or comments?**

Call toll free 1-844-384-3723 Monday through Friday 9AM – 5PM EST or [www.safrel.com](http://www.safrel.com)

### **Principal Display Panel**

#### **Compare to Tylenol® Simply Sleep active ingredients\***

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

Diphenhydramine HCl Tablets, 25 mg

Compare to Simply Sleep® Caplets active ingredient

NDC 71309-110-10

**Safrel®**  
**Nighttime Sleep Aid**

Diphenhydramine HCl 25 mg

- Helps You Fall Asleep
- Non-habit Forming
- Does NOT Contain Pain Reliever

easy to swallow 100 Caplets

**Drug Facts**

**Active ingredient (in each caplet)**  
Diphenhydramine HCl 25mg....Nighttime sleep-aid

**Uses** ■ For relief of occasional sleeplessness

**Directions**  
■ Adults and children 12 years and over: take 2 caplets at bedtime if needed or as directed by a doctor  
■ children under 12 years of age: do not use

**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  
■ a breathing problem such as emphysema or chronic bronchitis, difficulty in urination due to enlargement of the prostate gland  
DRUG FACTS CONTINUED on back of the label ▲

**DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING**

Lot. EXP.  
Distributed by: Safrel Pharmaceuticals  
Bridgewater, NJ 08807 USA  
www.safrel.com

No-Varnish Area

3 71309 11010 4

PEEL HERE

**Drug Facts (continued)**

Ask your doctor or pharmacist before use if you are taking sedatives or tranquilizers

**When Using this product**  
■ Use caution when driving a motor vehicle or operating machinery ■ Drowsiness will occur ■ avoid alcoholic beverages

**Stop use and ask a doctor if** Sleeplessness persists continuously more than 2 weeks. Insomnia may be a symptom of 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.

**Other Information**  
■ protect from moisture  
■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

**Inactive ingredients**  
colloidal silicon dioxide, croscarmellose sodium, dicalcium phosphate, fd&c blue #1 aluminum lake, fd&c blue #2 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, titanium dioxide, talc

**Questions or Comments? 1-844-384-3723**

STOP PEELING

## SLEEP-EZ NIGHTTIME SLEEP AID

diphenhydramine hcl 25 mg tablet, coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71309-110
<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	25 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>POLYVINYL ALCOHOL</b> (UNII: 532B59J990)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	

<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C BLUE NO. 2</b> (UNII: L06K8R7DQK)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>ANHYDROUS DIBASIC CALCIUM PHOSPHATE</b> (UNII: L11K75P92J)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	

### Product Characteristics

<b>Color</b>	blue	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	11mm
<b>Flavor</b>		<b>Imprint Code</b>	EC
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71309-110-25	25 in 1 BOX	06/01/2017	
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:71309-110-50	50 in 1 BOX	06/01/2017	
2		2 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:71309-110-02	2 in 1 POUCH	06/01/2017	
3		2 in 1 POUCH; Type 0: Not a Combination Product		
4	NDC:71309-110-10	100 in 1 BOTTLE	06/01/2017	
4	NDC:71309-110-01	1000 in 1 BOTTLE		
4	NDC:71309-110-05	500 in 1 BOTTLE		
4	NDC:71309-110-30	30 in 1 BOTTLE		
4		1 in 1 CARTON; 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	06/01/2017	

**Labeler** - Safrel Pharmaceuticals, LLC. (080566287)

