

**KROGER NIGHTTIME SLEEP AID- diphenhydramine hydrochloride tablet  
KROGER COMPANY**

*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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**Kroger NIGHTTIME SLEEP AID**

**Drug Facts**

**Active ingredient (in each caplet)**

Diphenhydramine HCl 25 mg

**Purpose**

Nighttime sleep-aid

**Use**

for the 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 ■ drowsiness will occur
- do not drive a motor vehicle or operate machinery

**Stop use and ask a doctor if**

sleeplessness persists continuously for 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.

**Drug Facts** (continued)

**Keep out of reach of children.**

### **Overdose warning**

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

### **Directions**

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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

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### **Other information**

- **each caplet contains:** calcium 23.52 mg
- store between 20-25°C (68-77°F). Avoid high humidity. Protect from light.

### **Inactive ingredients**

colloidal silicon dioxide, croscarmellose sodium, dicalcium phosphate, FD&C Blue #1, FD&C Blue #2, lecithin, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, talc, titanium dioxide

**Questions or comments? 1-800-632-6900**

### **PRINCIPAL DISPLAY PANEL**

COMPARE TO the active ingredient of SIMPLY SLEEP ® NIGHTTIME SLEEP AID CAPLETS\*

Kroger

NDC 30142-116-01

Nighttime Sleep-Aid

Diphenhydramine HCl, 25mg



# KROGER NIGHTTIME SLEEP AID

diphenhydramine hydrochloride tablet

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:30142-116
<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>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>ANHYDROUS DIBASIC CALCIUM PHOSPHATE</b> (UNII: L11K75P92J)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C BLUE NO. 2</b> (UNII: L06K8R7DQK)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

## 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>	S5
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30142-116-01	1 in 1 CARTON	04/16/2019	
1		100 in 1 BOTTLE; Type 0: Not a Combination Product		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part338	04/16/2019	

**Labeler** - KROGER COMPANY (006999528)

**Registrant** - Spirit Pharmaceuticals LLC (179621011)

Revised: 11/2022

KROGER COMPANY