

**MAXIMUM STRENGTH SLEEP AID- diphenhydramine hcl capsule, gelatin coated**  
**SPIRIT PHARMACEUTICALS LLC**

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**MAXIMUM STRENGTH SLEEP AID**

***Drug Facts***

***Active ingredient (in each softgel)***

Diphenhydramine HCl 50 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

***Stop use and ask a doctor if***

sleeplessness persist 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.

***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

## Inactive ingredients

FD&C Blue#1, gelatin, glycerin, polyethylene glycol-400, propylene glycol, sorbitol, titanium dioxide, water

## Questions or comments?

**1-888-333-9792**

## PRINCIPAL DISPLAY PANEL

SLEEP AID

Diphenhydramine HCl 50 mg  
100 Softgels



## MAXIMUM STRENGTH SLEEP AID

diphenhydramine hcl capsule, gelatin coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68210-4099
<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>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	

<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>WATER</b> (UNII: 059QF0KO0R)	

**Product Characteristics**

<b>Color</b>	blue	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	13mm
<b>Flavor</b>		<b>Imprint Code</b>	206;903
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-4099-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	07/02/2020	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M010	07/02/2020	

**Labeler - SPIRIT PHARMACEUTICALS LLC (179621011)**

Revised: 12/2023

SPIRIT PHARMACEUTICALS LLC