

**DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine  
hydrochloride capsule, liquid filled  
Strive Pharmaceuticals Inc.**

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**Nighttime Sleep-Aid  
Diphenhydramine HCl 50mg (Blue Softgel)**

Diphenhydramine HCl 50mg

Nighttime Sleep-aid

FD&C blue #1, FD&C red #40, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol, titanium dioxide

- do not take more than directed (see overdose warning)
- adults and children 12 years of age and over: take 1 softgel at bedtime if needed, or as directed by doctor
- children under 12 years of age: do not use

For relief of occasional sleeplessness

**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 asthma, emphysema or chronic bronchitis

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

**When using this product**

- drowsiness will occur
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery

**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.

**Overdose Warning:** In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as children even if you do not notice any signs or symptoms.

- store at room temperature between 20-25°C (68-77°F).

NDC 71852-715-90-1



# Nighttime Sleep-Aid

MAXIMUM STRENGTH non-habit forming

16 softgels

diphenhydramine HCl  
**50mg**  
each softgel



Compare to active ingredient in UNISOM® SleepGels®

RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION. **KEEP EVIDENT.** Do not use if printed seal is broken or missing.

### Drug Facts

**Active Ingredient (in each softgel)**  
Diphenhydramine HCl 50mg.....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 your doctor before use if you have:** ■ a breathing problem such as asthma, 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:** ■ drowsiness will occur ■ avoid alcoholic drinks ■ 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 serious underlying medical illness

**If pregnant or breast-feeding,** ask a health professional before use. **Keep out of reach of children.**

**OVERDOSE WARNING:** In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as children even if you do not notice any signs or symptoms.

**Directions:** ■ do not take more than directed (See overdose warning)

adults & children 12 years of age and over ■ take 1 softgel at bedtime if needed, or as directed by doctor

children under 12 years of age ■ do not use

**Other information:** ■ store between 20-25°C (68-77°F). Excursions permitted between 15°C-30°C (59-86°F)

**Questions or comments?** Call 1 (888) 677-8033

Distributed by: STRIVE PHARMACEUTICALS INC.  
East Brunswick, NJ 08816 | LB78561 | 1 RBX-00-02019

Lot No. \_\_\_\_\_

Exp. Date \_\_\_\_\_



# DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride capsule, liquid filled

## Product Information

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:70692-785

Route of Administration 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>WATER</b> (UNII: 059QF0KO0R)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>GELATIN, UNSPECIFIED</b> (UNII: 2G86QN327L)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	blue (greenish blue - transparent)	<b>Score</b>	no score
<b>Shape</b>	OVAL (Oblong)	<b>Size</b>	13mm
<b>Flavor</b>		<b>Imprint Code</b>	785
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70692-785-61	16 in 1 BOTTLE; Type 0: Not a Combination Product	08/20/2019	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M010	08/20/2019	

**Labeler** - Strive Pharmaceuticals Inc. (080028013)