

**NIGHTTIME SLEEP AID- diphenhydramine hydrochloride tablet, coated**  
**Strive Pharmaceuticals 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.*

-----  
**RIGHT REMEDIES Nighttime Sleep-Aid**

**Drug Facts**

**Active ingredient (in each caplet)**

Diphenhydramine HCl 25 mg

**Purpose**

Nighttime sleep-aid

**Use**

- 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 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.

**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**

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 19 mg
- store at room temperature between 20°-25°C (68°-77°F)
- avoid excessive heat, light and moisture.

### **Inactive ingredients**

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

### **Questions or comments?**

**1-888-577-8033** Monday - Friday 8am - 4pm EST

### **RIGHT REMEDIES**

Compare to the active ingredient of **TYLENOL®** Simply Sleep®\*

**helps you fall asleep  
safe, non-habit forming**

**TAMPER EVIDENT DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS  
BROKEN OR MISSING**

Distributed by: Strive Pharmaceuticals Inc., East Brunswick, NJ 08816

Product of India

Packaged and Quality Assured in the USA

READ AND KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

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

REV.00-032022

# Packaging



Compare to the active ingredient of **TYLENOL®** Simply Sleep®\*

NDC 70692-151-46

## Nighttime Sleep-Aid

DIPHENHYDRAMINE HCl, 25 mg  
Nighttime sleep-aid

helps you fall asleep  
safe, non-habit forming



Actual Size



Compare to the active ingredient of **TYLENOL®** Simply Sleep®\*

NDC 70692-151-46

## Nighttime Sleep-Aid

DIPHENHYDRAMINE HCl, 25 mg  
Nighttime sleep-aid

helps you fall asleep  
safe, non-habit forming



Actual Size



## Nighttime Sleep-Aid

helps you fall asleep  
safe, non-habit forming

READ AND KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

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



No Varnish

LOT:  
EXP:

<b>Drug Facts (continued)</b>	
<b>Warnings (continued)</b>	Take 2 caplets at bedtime
If you repeat or breast-feed, ask a health professional before use.	adults and children 12 years of age and over
Keep out of reach of children.	or as directed by a doctor
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.	do not use if you are under 12 years of age
	<b>Directions</b>
	Take 2 caplets at bedtime
	adults and children 12 years of age and over
	or as directed by a doctor
	do not use if you are under 12 years of age
	<b>Other information</b>
	each caplet contains: calcium 19 mg
	store at room temperature between 20°-25°C (68°-77°F)
	avoid excessive heat, light and moisture.
	<b>Inactive ingredients</b>
	crossarmallose sodium, dicalcium phosphate, FD&C blue #1, FD&C blue #2, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, silicon dioxide, lact, titanium dioxide
	<b>Questions or comments?</b>
	1-888-577-8088 Monday - Friday 8am - 4pm EST

Distributed by: Shine Pharmaceuticals Inc., East Brunswick, NJ 08816  
Product of India  
Packaged and Quality Assured in the USA

0.216

<b>DRUG FACTS TABLE</b>	
<b>Drug Facts</b>	<b>Purpose</b>
<b>Active ingredient (in each caplet)</b>	Nighttime sleep-aid
Diphenhydramine HCl, 25 mg	
<b>Use</b>	
for relief of occasional sleeplessness	
<b>Warnings</b>	
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.	

### DRUG FACTS TABLE

TAMPER EVIDENT DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

## Drug Facts

<b>Active ingredient (in each caplet)</b>	<b>Purpose</b>
Diphenhydramine HCl 25 mg.....	Nighttime sleep-aid

**Use**  
 ■ 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 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.**

## Drug Facts (continued)

**Warnings (continued)**  
 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**

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 19 mg  
 ■ store at room temperature between 20°-25°C (68°-77°F)  
 ■ avoid excessive heat, light and moisture.

**Inactive ingredients**  
 croscarmellose sodium, dicalcium phosphate, FD&C blue #1, FD&C blue #2, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, silicon dioxide, talc, titanium dioxide

**Questions or comments?**  
 1-888-577-8033 Monday - Friday 8am - 4pm EST

Distributed by: Strive Pharmaceuticals Inc., East Brunswick, NJ 08816  
 Product of India  
 Packaged and Quality Assured in the USA

## NIGHTTIME SLEEP AID

diphenhydramine hydrochloride tablet, coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70692-151
<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>CROSCARMELLOSE 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>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>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<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>	RECTANGLE	<b>Size</b>	12mm
<b>Flavor</b>		<b>Imprint Code</b>	DB
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70692-151-46	1 in 1 CARTON	04/06/2023	
1		72 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	04/06/2023	

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

Revised: 4/2023

Strive Pharmaceuticals Inc.