

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

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



72 caplets

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
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72 caplets

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No Varnish

LOT:
EXP:

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 drug

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, lact, titanium dioxide

Questions or comments?
1-888-577-4083 Monday - Friday 9am - 4pm EST
Product of India
Produced and Quality Assured in the USA

0.216

Drug Facts

Active ingredient (in each caplet)
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
or tranquilizers
Ask a doctor or pharmacist before use if you are taking sedatives

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	Drug Facts (continued)
Active ingredient	Warnings (continued)
Purpose	If pregnant or breast-feeding, ask a health professional before use.

(In each caplet)

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
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Questions or comments?

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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

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70692-151
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	blue	Score	no score
Shape	RECTANGLE	Size	12mm
Flavor		Imprint Code	DB
Contains			

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 Drug	M010	04/06/2023	

Labeler - Strive Pharmaceuticals Inc. (080028013)

Revised: 12/2024

Strive Pharmaceuticals Inc.