

DIPHENHYDRAMINE HYDROCHLORIDE 25MG- diphenhydramine hydrochloride

25mg tablet

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.

Nighttime Sleep-Aid

Sleep - Dormir

(Diphenhydramine HCl 25mg) - Blue caplet

Diphenhydramine HCl 25mg

croscarmellose sodium, D&C blue #4 aluminium lake, dibasic calcium phosphate, hydroxy propyl methyl cellulose, isopropyl alcohol, magnesium stearate, microcrystalline cellulose, polyethyl;ene glycol, talc, titanium dioxide

- take with a full glass of water
- do not take more than directed

adults and children 12 years of age and over	2 caplets at bedtime if needed, or as directed by a doctor
children under 12 years of age	do not use

for relief of occasional sleeplessness

Do not use

- in 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 a 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 accidental overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

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

Nighttime sleep-aid

- store at room temperature between 20 °C - 25 °C (68 °F - 77 °F)
- avoid high humidity
- protect from light

RIGHT REMEDIES
TYLENOL[®] Simply Sleep[®]
Nighttime Sleep-Aid
non habit forming helps you fall asleep
diphenhydramine HCl 25 mg each caplet
100 caplets
NDC 70692-111-01

RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION. TAMPER EVIDENT: Do not use if inverted safety seal under cap is broken or missing.

Drug Facts

Active Ingredient (in each caplet): Diphenhydramine HCl 25 mg.....Nighttime sleep aid
Purpose: for relief of occasional sleeplessness.

Warnings: Do not use: ■ in 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 ■ trouble urinating due to an enlarged prostate gland ■ glaucoma.

Ask a doctor or pharmacist before use if you are: ■ taking sedatives or tranquilizers.

When using this product: ■ drowsiness will occur ■ avoid alcoholic drinks ■ 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.

Directions: Adults & 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: ■ store at room temperature between 20-25°C (68-77°F). ■ avoid excessive heat, cold and humidity.

Questions or comments?:
Call 1 (888) 577-8033.

Distributed by: STRIVE PHARMACEUTICALS, INC.
East Brunswick, NJ 08816 | LB7069211101 | REV. 10/2018

Lot No. _____
Exp. Date _____



†compare to active ingredient in
TYLENOL® Simply Sleep®

NDC 70692-111-01

Nighttime Sleep-Aid

☾ non habit forming
helps you fall asleep

100
caplets

diphenhydramine HCl **25 mg** each caplet



Nighttime Sleep-Aid

☾ non habit forming
helps you fall asleep
diphenhydramine HCl 25mg

**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®.



†compare to active ingredient in
TYLENOL® Simply Sleep®

does NOT contain pain reliever

NDC 70692-111-01

Nighttime Sleep-Aid

☾ non habit forming
helps you fall asleep

100
caplets

diphenhydramine HCl
25 mg each caplet

Distributed by: STRIVE PHARMACEUTICALS INC.
East Brunswick, NJ 08816 - CT1101 - REV. 102018



3 70692 11101 9

COATING
FREE AREA

Lot. No.:

Exp. Date:

Drug Facts (continued)

Directions

- Do not take more than directed
- SEE OVERDOSE WARNING.
- take 2 caplets at bedtime if needed, or as directed by a doctor
- adults & children 12 years of age and over
- children under 12 years of age
- do not use

Other information

- store at room temperature between 20 - 25°C (68-77°F).
- avoid excessive heat, cold and humidity.
- close cap tightly after use.

Inactive Ingredients

colloidal silicon dioxide, croscarmellose sodium, D&C blue #4 aluminum lake, dibasic calcium phosphate, FD&C blue #1, FD&C blue #2, hydroxypropyl methyl cellulose, isopropyl alcohol, magnesium stearate, microcrystalline cellulose, polyethylene glycol, poly vinyl alcohol, talc*, titanium dioxide. *may contain.

Questions or comments?

Call 1 (888) 577-8033

Drug Facts

Active Ingredient (in each caplet) Purpose
Diphenhydramine HCl 25 mg Nighttime sleep aid

Uses

- for relief of occasional sleeplessness.

Do not use

- in 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
- trouble urinating due to an enlarged prostate gland
- glaucoma.

Ask a doctor or pharmacist before use if you are

- taking sedatives or tranquilizers.

When using this product

- drowsiness will occur
- avoid alcoholic drinks
- 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.

ADDITIONAL INFORMATION



DRUG FACTS

Active ingredient (in each caplet)	Purpose
Diphenhydramine HCl 25mg	Nighttime sleep-aid

Uses:
for relief of occasional sleeplessness

Warnings:

Do not use:

- in children under 12 years of age
- with any other product containing diphenhydramine, even one used on skin
- 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

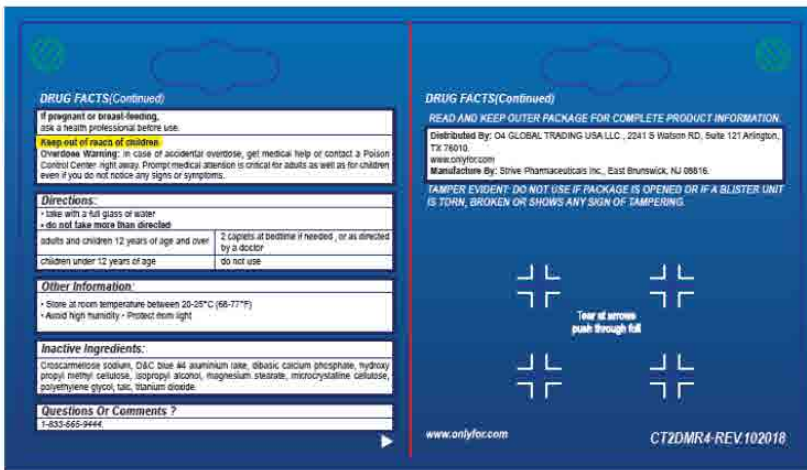
When using this product:

- 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.

LIFT PANEL FOR CONTINUED DRUG FACTS ▶



DRUG FACTS (Continued)

Keep out of reach of children.

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

Directions:

• take with a full glass of water	
• do not take more than directed	
adults and children 12 years of age and over	2 caplets at bedtime if needed, or as directed by a doctor
children under 12 years of age	do not use

Other Information:

- Store at room temperature between 20-25°C (68-77°F)
- Avoid high humidity • Protect from light

Inactive Ingredients:

Croscarmellose sodium, D&C blue #4 aluminum lake, dibasic calcium phosphate, hydroxypropyl methyl cellulose, isopropyl alcohol, magnesium stearate, microcrystalline cellulose, polyethylene glycol, talc, titanium dioxide

Questions Or Comments ?

1-833-666-9444

DRUG FACTS (Continued)

READ AND KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION.

Distributed By: O4 GLOBAL TRADING USA LLC, 2241 S Watson RD, Suite 121 Arlington, TX 76010
www.onlyfor.com

Manufacture By: Stive Pharmaceuticals Inc., East Brunswick, NJ 08816

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF A BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGN OF TAMPERING.

Tear at arrows
push through fill

www.onlyfor.com CT2DMR4-REV.102018

diphenhydramine hydrochloride 25mg tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70692-111
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
D&C BLUE NO. 4 (UNII: 0KSY80VYS3)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
TALC (UNII: 7SEV7J4R1U)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	

Product Characteristics

Color	blue	Score	no score
Shape	CAPSULE	Size	12mm
Flavor		Imprint Code	S1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70692-111-41	4 in 1 PACKAGE; Type 0: Not a Combination Product	12/20/2018	
2	NDC:70692-111-01	100 in 1 PACKAGE; Type 0: Not a Combination Product	01/29/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	12/20/2018	

Labeler - Strive Pharmaceuticals Inc (080028013)

