

TOPCARE SLEEP AID NIGHTTIME- diphenhydramine hydrochloride tablet, film coated

Topco Associates LLC

Topco Associates LLC. 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

- 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 pharmacist before use if you are

taking sedatives or tranquilizers

When using this product

- avoid alcoholic drinks
- drowsiness may 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 (1-800-222-2222).

Directions

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

Other information

- **each caplet contains:** calcium 15 mg
- store at 20-25°C (68-77°F). Avoid high humidity. Protect from light.
- **do not use if blister unit is broken or torn**

Inactive ingredients

carnauba wax, crospovidone, dibasic calcium phosphate dihydrate, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, pregelatinized starch, stearic acid, titanium dioxide

Questions or comments?

1-888-423-0139

Principal Display Panel

TopCare® health

COMPARE TO SIMPLY SLEEP® ACTIVE INGREDIENT

NIGHTTIME

Sleep Aid

DIPHENHYDRAMINE HCl 25 mg

NIGHTTIME SLEEP AID

- Helps You Fall Asleep
- Non Habit-Forming

Does Not Contain Pain Reliever

24 CAPLETS

actual size

+TopCare[®]
health

NIGHTTIME
Sleep Aid

DIPHENHYDRAMINE HCl 25 mg

NIGHTTIME SLEEP AID

NDC 3162-88-02

+TopCare[®]
health

COMPARE TO
SIMPLY SLEEP[®]
ACTIVE INGREDIENT*

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Sleep Aid

DIPHENHYDRAMINE HCl 25 mg

NIGHTTIME SLEEP AID

- Helps You Fall Asleep
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43162 88 C8

OPEN OTHER END

Drug Facts

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Drug Facts (continued)

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Questions or comments? 1-888-423-0139

*This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., distributor of Simply Sleep[®].

GLUTEN FREE

✓ QUALITY GUARANTEED

CONVENIENT RECLOSING TAB

DISTRIBUTED BY
TOPCO ASSOCIATES, LLC
ELK GROVE VILLAGE, IL 60007
©TOPCO PERA0521
QUESTIONS? 1-888-423-0139
topcare@topco.com
www.topcarebrand.com



Scan here for more
information or
call 1-888-423-0139



TOPCARE SLEEP AID NIGHTTIME

diphenhydramine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-431
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
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CROSPROVIDONE (120 .MU.M) (UNII: 68401960MK)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	BLUE (Light Blue)	Score	no score
Shape	OVAL	Size	11mm
Flavor		Imprint Code	L431
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC 36800 431			

1	NDC:36800-431-62	12 in 1 CARTON	09/11/2001	
1		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:36800-431-67	24 in 1 CARTON	01/27/2004	
2		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:36800-431-78	1 in 1 CARTON	09/13/2017	
3		100 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	09/11/2001	

Labeler - Topco Associates LLC (006935977)

Revised: 7/2024

Topco Associates LLC