

TOPCARE SLEEP AID NIGHTTIME- diphenhydramine hydrochloride tablet, film coated

Topco Associates LLC

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.

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*

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



43162 88 C8

OPEN OTHER END

Drug Facts

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Use for relief of occasional sleeplessness

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Drug Facts (continued)

Keep out of reach of children. Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions

adults and children 12 years and over	take 2 caplets at bedtime if needed, or as directed by a doctor
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Other information

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- do not use if blister unit is broken or torn

Inactive ingredients

camellia wax, croscollon, dibasic calcium phosphate dihydrate, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, poly sorbate 80, pregelatinized starch, stearic acid, titanium dioxide

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

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 TOPCO ASSOCIATES, LLC
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 topcare@topco.com
 www.topcarebrand.com



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 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 (15 MPAS AT 5%) (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 final	part338	09/11/2001	

Labeler - Topco Associates LLC (006935977)

Revised: 2/2023

Topco Associates LLC