

**SLEEP AID- diphenhydramine hydrochloride tablet, film coated
THIRTY MADISON 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.

Thirty Madison Inc 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
- 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

- 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 (1-800-222-1222).

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?

1-800-719-9260

Principal Display Panel

Non-habit forming

River

Sleep Aid

DIPHENHYDRAMINE HCl 25 mg

Nighttime Sleep Aid

24 CAPLETS

Does not contain pain reliever

Helps you fall asleep

Compare to Simply Sleep® Nighttime Sleep Aid active ingredient

Actual Size

River

Non-habit forming

Sleep Aid

DIPHENHYDRAMINE HCl 25 mg

Nighttime Sleep Aid
Does not contain pain reliever
Helps you fall asleep

24 CAPLETS

Drug Facts

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

Purpose 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 asthma or chronic bronchitis
■ glaucoma
■ trouble urinating due to an enlarged prostate gland

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When using this product
■ avoid alcoholic drinks
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■ sleeplessness persists continuously for more than 2 weeks; insomnia may be a symptom of serious underlying medical illness.

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Drug Facts (continued)

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Questions or comments? 1-800-719-9260

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



Distributed by
Thirty Madison, Inc.
New York, NY 10016

CONVENIENT RECLOSEING TAB

OPEN OTHER END

43162 TH C1

Compare to Simply Sleep® Nighttime Sleep Aid active ingredient*

Actual Size

SLEEP AID

diphenhydramine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71713-100
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)	
CROSPVIDONE (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

1	NDC:71713-100-51	12 in 1 CARTON	04/26/2022	
1		2 in 1 BLISTER PACK; 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	04/26/2022	

Labeler - THIRTY MADISON INC (080774087)

Revised: 4/2022

THIRTY MADISON INC