SLEEP AID- diphenhydramine hcl 25 mg tablet Ulai Health 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.

Drug Facts

Active ingredient (in each caplet)

Diphenhydramine HCl 25 mg

Purpose

Nighttime sleep aid

Uses

helps reduce difficulty falling asleep

Warnings

Do not use

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

Ask a doctor before use if you have

- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- 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
- use caution when driving a motor vehicle or operating 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.

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	take 2 caplets at bedtime if needed, or as directed by
and over	your doctor

Other information

- each caplet contains: calcium 15 mg
- store at 20-25 °C (68-77 °F)

Inactive ingredients

colloidal silicon dioxide, corn startch, FD&C blue #1, dicalcium phosphate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, stearic acid, talc, titanium dioxide

Questions or comments?

(866) 562-2756 (Mon-Fri 8 AM to 4 PM EST)

PHARBEST

NDC 73057-358-06

Manufactured in the USA

Safe, Non-habit forming

Sleep Aid

*Compare to the active ingredient in Sominex ®

Diphenhydramine HCI 25 mg

Nighttime Sleep Aid

50 CAPLETS



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SLEEP AID

diphenhydramine hcl 25 mg tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73057-358
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	blue (Light Blue color)	Score	no score
Shape	CAPSULE (Capsule Shaped Tablet)	Size	12mm
Flavor		Imprint Code	PH25
Contains			

l	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:73057-358-06	50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/02/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part338	07/02/2019	

Labeler - Ulai Health LLC (081181535)

Revised: 1/2022 Ulai Health LLC