

HELP I CANT SLEEP - diphenhydramine tablet

Help Remedies, 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.

Drug Facts

**Active Ingredient.....Purpose
(in each caplet)**

Diphenhydramine HCl 25 mg.....Nighttime/sleep aid

Use: For relief of occasional sleeplessness

Warnings

- 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 after use.
- Stop and ask a doctor if sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of a serious underlying medical illness

Do not use

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

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)

If pregnant or breast feeding, ask a health professional before use.

Directions

- do not take more than directed
- adults and children 12 years 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

- each caplet contains: calcium 23mg.
- store at room temperature 25°C (77°F) excursions permitted between 15-30°C (59-86°F)
- avoid excessive heat and humidity .
- use by expiration date on package.
- do not use if packet is torn, cut or opened.
- keep carton. They contain important information.

Inactive Ingredients

carnauba wax, colloidal silicon dioxide, croscarmellose sodium, dibasic calcium phosphate dihydrate, hypromellose, magnesium stearate, microcrystalline cellulose, polyethelene glycol, polysorbate 80, titanium dioxide.

Distributed by Help Remedies,
57 W. 28th St. Fl. 4
New York, NY 10001
www.helpneedhelp.com

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page 2
typ 1.9375"

page 3
typ 1.8125"

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Base Web
2.25" X 2.25" label size

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HELP I CANT SLEEP

diphenhydramine tablet

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:49260-613

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)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	

Product Characteristics

Color	white (white)	Score	no score
Shape	OVAL (Oval Tablet)	Size	11mm
Flavor		Imprint Code	h;help
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49260-613-50	50 in 1 BOTTLE		
2	NDC:49260-613-16	16 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part336	07/01/2009	

Labeler - Help Remedies, Inc. (050359682)

Registrant - Help Remedies, Inc. (050359682)