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

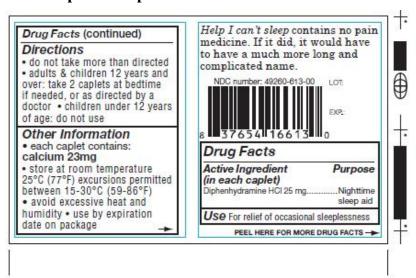
Other Information

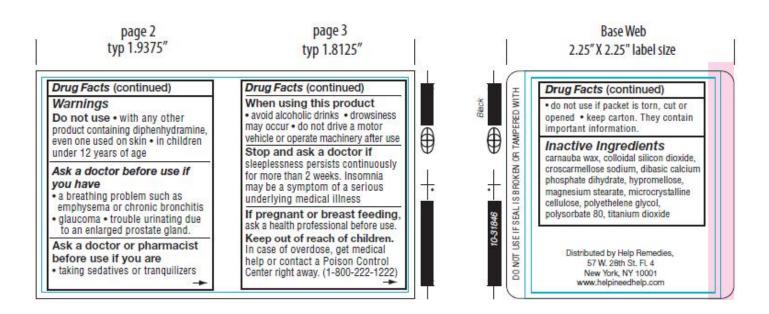
- each caplet contains: calcium 23mg.
- store at room temperature 25°C (77°F) excursions permitted between 15-30°C (59-86°F)
- avoid excessive heat and humidity.
- use by expiration date on package.
- do not use if packet is torn, cut or opened.
- keep carton. They contain important information.

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.helpineedhelp.com







Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DIPHENHYDRAMINE HYDRO CHLO RIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg	

Inactive Ingredients		
Ingredient Name	Strength	
CARNAUBA WAX (UNII: R12CBM0EIZ)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)		
DIBASIC CALCIUM PHO SPHATE DIHYDRATE (UNII: O7TSZ97GEP)		
HYPROMELLOSES (UNII: 3NXW29 V3WO)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)		
POLYSORBATE 80 (UNII: 6OZP39ZG8H)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)		

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

F	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)

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