

NIGHTTIME SLEEP EASY- diphenhydramine hcl tablet
P and L Development of New York Corporation (ReadyInCase)

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.

Nighttime Sleep Easy

Active ingredient (in each caplet)

Diphenhydramine HCl 25 mg

Purpose

Nighttime sleep-aid

Uses

provides relief of occasional sleeplessness

Warnings

Do not use

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

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

- drowsiness will occur
- avoid alcoholic drinks
- 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 a serious underlying medical illness.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

Overdose Warning: In the case of overdose, get medical help or contact a Poison Control Center right away.

Directions

Do not take more than directed

- **adults and children 12 years of age 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 25 mg**
- store at controlled room temperature 15°-30°C (59°-86°F)
- avoid excessive heat and humidity

Inactive ingredients

carnauba wax*, colloidal silicon dioxide*, croscarmellose sodium, dibasic calcium phosphate dihydrate, FD&C blue #1 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, talc, titanium dioxide

*contains one or more of these ingredients

Questions or comments?

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

PRINCIPAL DISPLAY PANEL

Compare to the active ingredient in **Tylenol® Simply Sleep®**†

readyincase™

nighttime

sleep-aid

diphenhydramine HCl 25 mg

non-habit forming

fall asleep fast wake up rested

does not contain pain reliever

caplets

†This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Tylenol® Simply Sleep®.

Distributed by:

PL Developments

200 Hicks Street

Westbury, NY 11590

Product Labeling

KEEP OUTER CARTON FOR COMPLETE
WARNINGS AND PRODUCT INFORMATION.

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER
UNITS IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.

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Consumer Healthcare, owner of the registered trademark
Tylenol® Simply Sleep®.

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Drug Facts (continued)

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nighttime
sleep-aid
diphenhydramine HCl 25 mg



Compare to the active ingredient
in **Tylenol® Simply Sleep®**

NDC 59726-400-12

nighttime
sleep-aid
diphenhydramine HCl 25 mg
non-habit forming

fall asleep fast wake up rested

does not contain pain reliever

12 caplets



Distributed by:
PL Developments
200 Hicks Street
Westbury, NY 11590

PLD-B
FC002010



Readyincase Nighthtime Sleep-aid

NIGHTTIME SLEEP EASY

diphenhydramine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59726-400
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)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	BLUE (blue)	Score	no score
Shape	CAPSULE	Size	11mm

Flavor		Imprint Code	T129;S25	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59726-400-12	12 in 1 BOX		
1		12 in 1 BLISTER PACK		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL	part338	12/04/2012		

Labeler - P and L Development of New York Corporation (ReadyInCase) (800014821)

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P and L Development of New York Corporation (ReadyInCase)