

SLEEPINAL- diphenhydramine hydrochloride capsule

Blairex Laboratories, 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 (in each capsule)

Diphenhydramine hydrochloride 50 mg

Purpose

night-time 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
- glaucoma
- trouble urinating due to the enlargement of the prostate gland

Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives

When using this product avoid alcoholic drinks.

Stop use and ask 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. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

Adults and children 12 years and over:

- take 1 capsule at bedtime if needed, or as directed by a doctor.

Other information

- store at 15-30°C (59-86°F)
- protect from excessive moisture
- protect from light
- retain product in box until administered

Inactive ingredients

FD&C blue no. 1, FD&C red no. 3, gelatin, lactose, magnesium stearate, talc

Manufactured for:

Blairex Laboratories, Inc.

P.O. Box 2127 Columbus, IN 47202 USA

Questions or Comments? Call TOLL FREE 1-800-252-4739

www.sleepinal.net

MAXIMUM STRENGTH

Sleepinal[®]

Night-time Sleep-Aid CAPSULES

NDC 50486-616-32

Non-habit Forming

One Capsule Dosage

Wake Up Refreshed

32 Capsules

Diphenhydramine Hydrochloride

PACKAGE NOT CHILD RESISTANT

Safe Restful Sleep

Contains the sleep-aid ingredient doctors recommend most.

TAMPER EVIDENT FEATURE see back panel

In clinical studies, people who had difficulty falling asleep, fell asleep faster and got a restful night's sleep after taking the active ingredient in Sleepinal®.

B00-000014-06

MAXIMUM STRENGTH
SLEEPINAL®
Night-time Sleep-Aid CAPSULES

MAXIMUM STRENGTH NDC 50486-616-32
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3. Sleepinal® appears on each capsule half.
Do not use if Sleepinal® name is
not clearly visible or is missing.

Safe Restful Sleep

Contains the sleep-aid ingredient doctors recommend most.

TAMPER EVIDENT FEATURE see back panel

In clinical studies, people who had difficulty falling asleep, fell asleep faster and got a restful night's sleep after taking the active ingredient in Sleepinal.[®]

B00-000010-05

NDC 50486-616-16

MAXIMUM STRENGTH

SLEEPINAL[®]

Night-time Sleep-Aid CAPSULES

-  Non-habit Forming
-  One Capsule Dosage
-  Wake Up Refreshed

16 Capsules
Diphenhydramine Hydrochloride

MAXIMUM STRENGTH
SLEEPINAL[®]
Night-time Sleep-Aid CAPSULES

MAXIMUM STRENGTH
SLEEPINAL[®]
Night-time Sleep-Aid CAPSULES

MAXIMUM STRENGTH
SLEEPINAL[®]
Night-time Sleep-Aid CAPSULES

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	50 mg

Inactive Ingredients

Ingredient Name	Strength
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
TALC (UNII: 7SEV7J4R1U)	
MAGNESIUM STEARATE (UNII: 70097M6I3O)	
GELATIN (UNII: 2G86QN327L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	

Product Characteristics

Color	blue (transparent)	Score	no score
Shape	CAPSULE (CAPSULE)	Size	19mm
Flavor		Imprint Code	SLEEPINAL;
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50486-616-32	4 in 1 CARTON	10/01/1999	
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:50486-616-16	2 in 1 CARTON	10/01/1999	
2		8 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	10/01/1999	

Labeler - Blairex Laboratories, Inc. (092575133)