

SLEEP ORIGINAL FORMULA- diphenhydramine hcl tablet
Best Choice (Valu Merchandisers Company)

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 tablet)

Diphenhydramine HCl 25 mg

Purpose

Nighttime sleep-aid

Use

helps reduce difficulty falling asleep

Warnings

Do not give to children under 12 years of age.

Do not use this product

with other products containing diphenhydramine, even one used on skin

Ask a doctor before use if you have

- emphysema
- chronic bronchitis
- glaucoma
- difficulty in urination due to an enlargement of the prostate gland

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers

When using this product

avoid alcoholic beverages.

stop use and ask a doctor if

- sleeplessness persists for more than 2 weeks. Insomnia may be a symptom of a serious underlying medical illness.

If pregnant or breast-feeding,

ask a health care 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 2 tablets at bedtime if needed or as directed by a doctor. For best results, take recommended dose.

Other information

- **each tablet contains:** calcium 65 mg
- store at controlled room temperature 15°-30°C (59°-86°F)
- avoid excessive heat and humidity

Inactive ingredients

croscarmellose sodium, dicalcium phosphate, FD&C Blue #1 aluminium lake, magnesium stearate and microcrystalline cellulose

May also contain: silicon dioxide and stearic acid

Principal Display Panel

Compare to the active ingredient in Somnex®*

*This product is not manufactured or distributed by Glaxosmithkline, owner of the registered trademark Somnex®

SLEEP TABLETS

wake rested and refreshed

Nighttime Sleep-Aid

Diphenhydramine HCl 25 mg

PROUDLY DISTRIBUTED BY:

VALU MERCHANDISERS, CO.

KANSAS CITY, MO 64111

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

THIS PRODUCT IS PACKAGED IN A CHILD RESISTANT AND TAMPER EVIDENT PACKAGE. USE ONLY IF BLISTERS ARE INTACT.

Product Label



Original Formula

Original Formula Sleep Tablets

COMPARE TO THE ACTIVE INGREDIENT IN SOMINEX®



Sleep Tablets

Wake Rested and Refreshed
Nighttime Sleep-Aid

DIPHENHYDRAMINE HCl 25mg



16 TABLETS, 25 mg EACH

THIS PRODUCT IS PACKAGED IN A CHILD RESISTANT AND TAMPER EVIDENT PACKAGE. USE ONLY IF BLISTERS ARE INTACT.

Lot No.:
Exp. Date:



PROUDLY DISTRIBUTED BY:
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KANSAS CITY, MO 64111

PLD 10/05
F20BC16

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Original Formula
Sleep Tablets

Drug Facts
Active Ingredient (in each tablet) Diphenhydramine HCl 25 mg.....Nighttime sleep-aid
Purpose Use helps to reduce difficulty falling asleep.
Warnings Do not give to children under 12 years of age. Do not use this product with other products containing diphenhydramine, even one used on skin. Ask a doctor before use if you have ■ emphysema ■ chronic bronchitis ■ glaucoma ■ difficulty in urination due to enlargement of the prostate gland Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers. When using this product avoid alcoholic beverages. Stop use and ask a doctor if ■ sleepiness persists for more than 2 weeks Insomnia may be a symptom of a serious underlying medical illness. If pregnant or breast-feeding, ask a health care professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.
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Nighttime sleep-aid

SLEEP ORIGINAL FORMULA

diphenhydramine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63941-200
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
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ALUMINUM OXIDE (UNII: LM26O6933)	

Product Characteristics

Color	BLUE	Score	2 pieces
Shape	ROUND	Size	10mm
Flavor		Imprint Code	1008;1008
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63941-200-16	2 in 1 CARTON	07/16/2010	07/16/2020
1		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	part336	07/16/2010	07/16/2020

Revised: 7/2019

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