NIGHTTIME SLEEP AID- diphenhydramine hcl capsule Valu Merchandisers Company (Best Choice)

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 softgel)

Diphenhydramine HCl 50 mg

Purpose

Nighttime sleep- aid

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 an enlargement of the prostate gland

Ask doctor or pharmacist before use if you are now 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 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 of age and over**: take 1 softgel at bedtime if needed or as directed by a doctor

Other information

- Store at controlled room temperature 15°-30°C (59°-86°F)
- *This product is not manufactured or distributed by Chattem, Inc., owner of the registered trademark Maximum Strength Unisom SleepGels®

Inactive ingredients

edible white ink, FD&C Blue #1, gelatin, glycerin, polyethylene glycol, purified water and sorbitol special.

Questions or comments?

call toll free 1-877-753-3935

Principal Display Panel

*Compare to the Active Ingredient in Maximum Strength Unisom SleepGels®

Nighttime Sleep Aid

Diphenhydramine HCl 50 mg

Helps to reduce difficulty falling asleep

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Product Label



Maximum Strength

Helps to reduce difficulty falling asleep

DIPHENHYDRAMINE HYDROCHLORIDE, 50 mg

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

DATE NO.:

LOT

HEALTA Best Choice! CARE

NIGHTTIME

DIPHENHYDRAMINE HYDROCHLORIDE, 50 mg

Helps to reduce difficulty falling asleep

16 SOFTGELS เเเ

ONE SOFTGEL PER DOSE

BEST CHOICE



Purpose

PROUDLY DISTRIBUTED BY: VALU MERCHANDISERS, CO. KANSAS CITY, MO 64111

PLD-B F23BC16

Questions or comments? Call toll free: 1-877-753-3935

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When using this product avoid alcoholic beverages. Ask a doctor or pharmacist before use it you are now taking sedatives or tranquilizers.

Ask a doctor before use if you have — emphysems — chronic bronchilds — glaucoms — difficulty in unimation due to an enlargement of the prostate gland Do not use this product with other products containing diphenhydramine, even one used on skin.

Do not give to children under 12 years of age. Warnings

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Orug Facts

NIGHTTIME SLEEP AID

diphenhydramine hcl capsule

Prod	luct	Info	rma	tion
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Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63941-230
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Route of Administration ORAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Froudet Characteristics			
Color	BLUE	Score	no score
Shape	CAPSULE	Size	13mm
Flavor		Imprint Code	P50;A99
Contains			

Packaging

	1 ackaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:63941-230-16	2 in 1 CARTON			
1		8 in 1 BLISTER PACK			

Marketing Information

8			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	07/26/2010	

Labeler - Valu Merchandisers Company (Best Choice) (868703513)

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

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Valu Merchandisers Company (Best Choice)