NIGHTTIME SLEEP AID- diphenhydramine hydrochloride tablet 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.

1019-BST-2021-1116

Drug Facts

Active ingredient (in each tablet)

Diphenhydramine HCl 25 mg

Purpose

Nighttime sleep-aid

Use

helps to reduce difficulty falling asleep

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 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 will occur
- 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 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 (1-800-222-1222).

Directions

- adults and children 12 years of age and over: take two tablets at bedtime if needed, or as directed by a doctor
- children under 12 years of age: do not use

Other information

- each tablet contains: calcium 85 mg
- store between 20-25°C (68-77°F)
- retain carton for complete product information

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, dibasic calcium phosphate, FD&C blue #1 aluminum lake, magnesium stearate, microcrystalline cellulose

PRINCIPAL DISPLAY PANEL

COMPARE TO THE ACTIVE INGREDIENT IN SOMINEX®†

Best Choice®

ORIGINAL FORMULA

NIGHTTIME

Sleep-Aid

Actual Size

Diphenhydramine HCl

- Helps You Fall Asleep
- Safe, Effective & Non-Habit Forming

16 TABLETS

25 MG EACH



	Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63941-219
ı	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	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)		
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
ALUMINUM OXIDE (UNII: LMI26O6933)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)		

Product Characteristics				
Color	blue	Score	no score	
Shape	ROUND	Size	10mm	
Flavor		Imprint Code	93XF;57344	
Contains				

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:63941-219- 01	4 in 1 CARTON	01/19/2017			
1		4 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	01/19/2017		

Labeler - VALU MERCHANDISERS COMPANY (868703513)