NIGHTTIME SLEEP AID- diphenhydramine hydrochloride capsule, liquid filled SPIRIT PHARMACEUTICALS LLC

VALUMEDS NIGHTTIME SLEEP-AID

Drug Facts

Active ingredient (in each softgel)

Diphenhydramine HCL 50 mg

Purpose

Nighttime sleep-aid

Uses

for relief of occasional sleeplessness

Warnings

Do not use

- for 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

Stop use and ask a doctor if

sleeplessness persist 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: 1 softgel (50 mg) at bedtime if needed, or as directed by a doctor

Inactive ingredients

FD&C Blue#1, gelatin, glycerin, polyethylene glycol-400, propylene glycol, sorbitol, titanium dioxide, water

Questions or comments?

1-888-333-9792

PRINCIPAL DISPLAY PANEL

VALUMEDS™

Compare to the active ingredient

in UNISOM®*

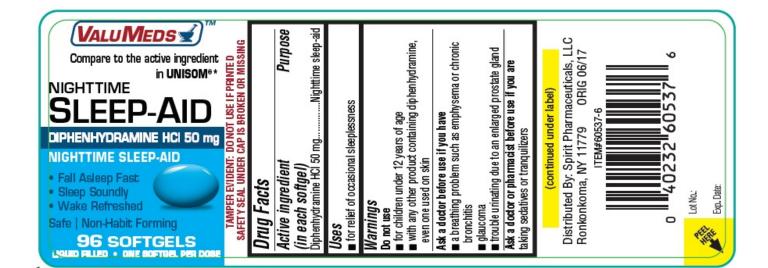
NIGHTTIME

SLEEP-AID

DIPHENHYDRAMINE HCI 50 mg

NIGHTTIME SLEEP-AID

Fall Asleep Fast Sleep Soundly Wake Refreshed Safe/Non-Habit Forming



Orug Facts (continued)

When using this product

avoid alcoholic drinks

sleeplessness persist continuously for more than 2 weeks. Insomnia may be a symptom of serious Stop use and ask a doctor if

underlying medical illness.

If pregnant or breast-feeding,

ask a health professional before use.

In case of overdose, get medical help or contact a Poison Control Center nght away. 1(800)222-1222 Keep out of reach of children.

Directions

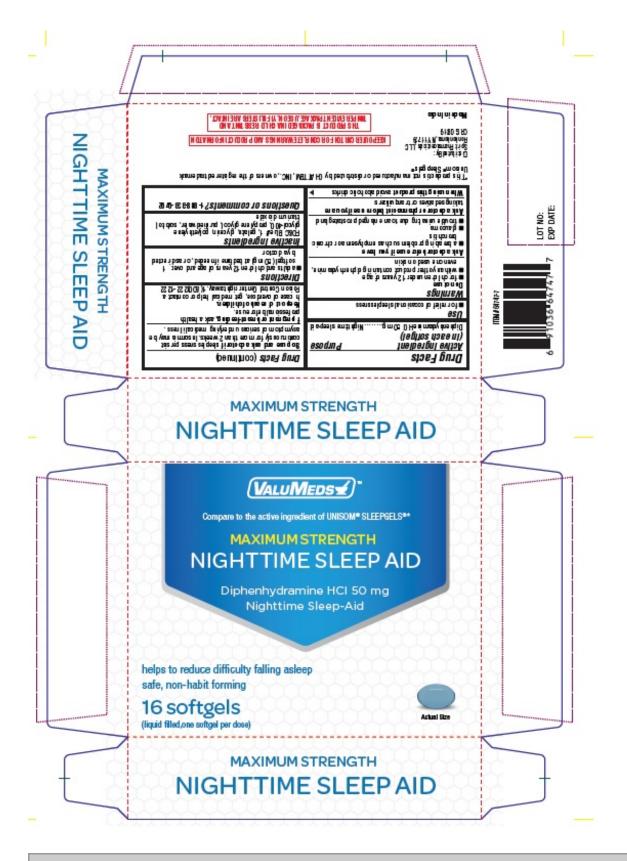
adults and children 12 years of age and over: 1 soffgel (50 mg) at bedtime if needed, or as directed by a doctor

nactive ingredients

FD&C Blue # 1, gelatin, glycerin, polyethylene glycol-400 propylene glycol, sorbitol, titanium dioxide, water

Questions or comments? 1-888-333-9792

*This product is not manufactured or distributed by CHATTEM, INC., owners of the registered trademark Unisom®



NIGHTTIME SLEEP AID

diphenhydramine hydrochloride capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-2020
Route of Administration	ORAL		

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		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
GELATIN (UNII: 2G86QN327L)			
GLYCERIN (UNII: PDC6A3C0OX)			
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
SORBITOL (UNII: 506T60A25R)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
WATER (UNII: 059QF0KO0R)			

Product Characteristics				
Color	blue	Score	no score	
Shape	OVAL	Size	13mm	
Flavor		Imprint Code	206	
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:68210- 2020-0	96 in 1 BOTTLE; Type 0: Not a Combination Product	04/16/2018		
2	NDC:68210- 2020-1	2 in 1 CARTON	03/12/2020		
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 Drug	M010	04/16/2018		

Labeler - SPIRIT PHARMACEUTICALS LLC (179621011)

Revised: 12/2023 SPIRIT PHARMACEUTICALS LLC