

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

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**VALUMEDS NIGHTTIME SLEEP-AID**

***Drug Facts***

***Active ingredients (in each softgel)***

Diphenhydramine HCl 25 mg

***Purpose***

nighttime sleep-aid

***Uses***

- for the relief of occasional sleeplessness
- reduces time to fall asleep if you have difficulty falling asleep

***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 asthma, emphysema, or chronic bronchitis
- glaucoma
- difficulty in urination due to enlargement of the prostate gland
- heart disease

**Ask a doctor or pharmacist before use if you are** taking sedatives, tranquilizers or any other sleep aid

**When using this product**

- avoid alcoholic beverages and other drugs that cause drowsiness
- drowsiness will occur
- be careful when driving a motor vehicle or operating 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.** Overdose warning: Taking more than directed can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away. 1(800)222-1222

**Directions**

- take only one dose per day (24 hours) - see Overdose warning

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adults & children 12 yrs & over	One dose= TWO 25 mg softgels (50 mg) at bed time if needed or as directed by a doctor
children under 12 years	Do not use

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**Other information**

- store at 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F) and high humidity
- Protect from light

**Inactive ingredients**

FD&C Blue#1, FD&C Red#40, gelatin, glycerin, polyethylene glycol-400, propylene glycol, sorbitol sorbitan, titanium dioxide

**Questions or comments?**

**1-888-333-9792**

Distributed By:

Spirit Pharmaceuticals, LLC

Ronkonkoma, NY 11779

**PRINCIPAL DISPLAY PANEL - 48 COUNT BLISTER CARTON**

**VALUMEDS™**

**Compare to the active ingredient**

in **ZzzQuil®\***

**NIGHTTIME**

**SLEEP-AID**

**DIPHENHYDRAMINE HCl 25 mg**

**Non Habit-Forming**

Not for Treating Cold or Flu

See Warnings

**48 SOFTGELS**



**NIGHTTIME SLEEP-AID**  
 DIPHENHYDRAMINE HCl 25 mg  
 48 SOFTGELS



**NIGHTTIME SLEEP-AID**

DIPHENHYDRAMINE HCl 25 mg

**48 SOFTGELS**  
 Non Habit-Forming  
 Not for Treating Cold or Flu  
 See Warnings



Compare to the active ingredient  
 in ZzzQuil®\*

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

LOT:  
 EXP:



0 402332760534 5  
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 Spirit Pharmaceuticals, LLC  
 Ronkonkoma, NY 11779  
 ORIG 06/17

**Questions or comments? 1-888-333-9792**

**Drug Facts (continued)**  
 ■ ask a doctor before use if you have a breathing problem such as asthma, emphysema, or chronic bronchitis ■ heart disease ■ difficulty in urination due to enlargement of the prostate gland ■ glaucoma ■ ask a doctor or pharmacist before use if you are taking sedatives, tranquilizers or any other sleep aid ■ When using this product ■ avoid alcoholic beverages and other drugs that cause drowsiness ■ drowsiness will occur ■ be careful when driving a motor vehicle or operating machinery ■ Stop use and ask a doctor if sleepiness 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. Overdose warning: Taking more than directed can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away; 1(800)222-1222. ■ Directions ■ Take only one dose per day (24 hours) - see Overdose warning ■ Adults & children 12 yrs & over One dose = TWO 25 mg softgels (50 mg) at bed time if needed or as directed by a doctor ■ Children under 12 years Do not use. ■ Other information ■ store at 20° C (68°-77° F) ■ avoid excessive heat above 40° C (104° F) and high humidity ■ Protect from light ■ Inactive ingredients FD&C Blue #1, FD&C Red #40, gelatin, glycerin, polyethylene glycol-400, propylene glycol, sorbitol sorbitan, titanium dioxide

**Drug Facts**  
 Active ingredients (in each softgel)  
 Diphenhydramine HCl 25 mg  
 Diphthaline sleep-aid  
**Uses**  
 ■ for the relief of occasional sleeplessness  
 ■ reduces time to fall asleep if you have difficulty falling asleep  
**Warnings**  
 Do not use  
 ■ for children under 12 years of age  
 ■ with any other product containing diphenhydramine, even one used on skin.

# NIGHTTIME SLEEP AID

diphenhydramine hydrochloride capsule, liquid filled

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68210-2010
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	purple	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	15mm
<b>Flavor</b>		<b>Imprint Code</b>	602
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-2010-0	48 in 1 CARTON	04/16/2018	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:68210-2010-1	1 in 1 CARTON	04/16/2018	
2		12 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