

**VALUMEDS NIGHTTIME SLEEP AID- diphenhydramine hydrochloride tablet  
SPIRIT PHARMACEUTICALS LLC**

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**VALUMEDS NIGHTTIME SLEEP AID CAPLETS**

***Drug Facts***

***Active ingredients (in each caplet)***

Diphenhydramine HCl 25mg

***Purpose***

nighttime sleep-aid

***Uses***

for the 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
- 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.**

**Overdose warning**

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

## Directions

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adults and children 12 years and over	take 2 caplets at bedtime if needed, or as directed by a doctor
children under 12 years	do not use

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## ***Other information***

**each caplet contains:** calcium 23.52 mg

store between 20-25°C(68-77°F). Avoid high humidity. Protect from light.

## ***Inactive ingredients***

Colloidal silicon dioxide, croscarmellose sodium, dicalcium phosphate, FD&C Blue#1, FD&C Blue#2, lecithin, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, talc, titanium dioxide

## **Questions or comments?**

1-888-333-9792

Distributed By: Spirit Pharmaceuticals, LLC

Ronkonkoma, NY 11779

## **PRINCIPAL DISPLAY PANEL - 36 COUNT BOTTLE CARTON**

**VALUMEDS™**

**Compare to the active ingredient**

in **TYLENOL® SIMPLY SLEEP®\***

**NIGHTTIME**

**SLEEP AID**

**DIPHENHYDRAMINE HCl 25 mg**

NON-HABIT FORMING

DOES NOT CONTAIN PAIN RELIEVER

**36 CAPLETS**



## VALUMEDS NIGHTTIME SLEEP AID

diphenhydramine hydrochloride tablet

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68210-0203
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>ANHYDROUS DIBASIC CALCIUM PHOSPHATE</b> (UNII: L11K75P92J)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C BLUE NO. 2</b> (UNII: L06K8R7DQK)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

**Product Characteristics**

<b>Color</b>	blue	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	11mm
<b>Flavor</b>		<b>Imprint Code</b>	S5
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-0203-3	1 in 1 CARTON	04/10/2018	
1		36 in 1 BOTTLE; Type 0: Not a Combination Product		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC Monograph Drug	M010	04/10/2018	

