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

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#### **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

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

#### 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

# PRINCIPAL DISPLAY PANEL

Nighttime sleep aid Diphenhydramine HCl 25 mg - Nighttime Sleep-Aid

Helps reduce difficulty falling asleep

Non-habit forming

Not for treating pain, cold or flu

12 Softgels



12 softgels

# nighttime sleep aid

Diphenhydramine HCl 25 mg - Nighttime Sleep-Aid

Helps reduce difficulty falling asleep Non-habit forming *Not for treating pain, cold or flu* 



NIGHTTIME SLEEP A	ID				
diphenhydramine hydrochlor	ide capsule, liquid fillec	ł			
Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:68210-4131	
Route of Administration	ORAL				
<b>Active Ingredient/Active</b>	Moiety				
Ingredient Name Basis of St				rength	Strength
DIPHENHYDRAMINE HYDROCHL (DIPHENHYDRAMINE - UNII:8GTS825		DIPHENHYDRAMINE HYDROCHLORIDE		25 mg	
In a star In our distants					
Inactive Ingredients					
Ingredient Name					ength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)					
FD&C RED NO. 40 (UNII: WZ B912	27XOA)				
GELATIN (UNII: 2G86QN327L)					
GLYCERIN (UNII: PDC6A3C0OX)					
POLYETHYLENE GLYCOL 400 (U	INII: B697894SGQ)				
PROPYLENE GLYCOL (UNII: 6DC9	Q167V3)				
SORBITOL (UNII: 506T60A25R)					
TITANIUM DIOXIDE (UNII: 15FIX9)	V2JP)				

Pr	oduct Chara	cterist	tics						
		purple	Score		no score				
		CAPSULE							
		CAPSULE	Size		15mm				
	avor Imprint Cod		Imprint Code		602				
Co	ntains								
Packaging									
#	ltem Code		Package Description		Marketing Start Date	Marketing End Date			
	NDC:68210- 4131-1	1 in 1 CA	in 1 CARTON		04/27/2021				
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product							
		<b>F</b>							
	Marketing Information								
Μ	arketing								
Μ	Marketing Category	Ар	plication Number or Citation	Monograph	Marketing Start Date	Marketing End Date			

# Labeler - SPIRIT PHARMACEUTICALS LLC (179621011)

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SPIRIT PHARMACEUTICALS LLC