

NIGHTTIME SLEEP AID- diphenhydramine hydrochloride capsule, liquid filled
Spirit Pharmaceuticals LLC

Nighttime Sleep Aid

Drug Facts

Active Ingredient (in each tablet)

Diphenhydramine Hydrochloride 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 emphysema or chronic bronchitis • glaucoma
• difficulty in urination due to enlargement of the prostate gland

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers

When using this product • avoid alcoholic beverages

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

take only one dose per day (24 hours)

adults & children 12 years & over	take 2 softgels at bedtime if needed or 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, propylene glycol, purified water, sorbitol sorbitan solution, titanium dioxide

Questions or comments?

1-888-333-9792

Distributed By:

Spirit Pharmaceuticals, LLC

Ronkonkoma, NY 11779

Made in India

Carton



NIGHTTIME SLEEP AID

diphenhydramine hydrochloride capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-4195
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
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O921CV9RU)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	purple	Score	no score
Shape	OVAL	Size	15mm
Flavor		Imprint Code	602
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-4195-2	24 in 1 BLISTER PACK; Type 0: Not a Combination Product	12/28/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M010	12/28/2021	

Labeler - Spirit Pharmaceuticals LLC (179621011)

Revised: 12/2023

Spirit Pharmaceuticals LLC