MAXIMUM STRENGTH SLEEP AID- diphenhydramine hcl capsule, gelatin coated SPIRIT PHARMACEUTICALS LLC

MAXIMUM STRENGTH SLEEP AID

Drug Facts

Active ingredient (in each softgel)

Diphenhydramine HCl 50 mg

Purpose

Nighttime sleep-aid

Use

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 Stop use and ask a doctor if

sleeplessness persist continuosly 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

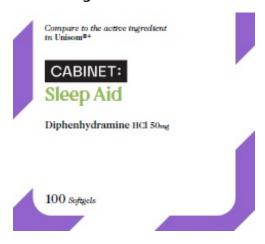
FD&C Blue#1, gelatin, glycerin, polyethylene glycol-400, propylene glycol, sorbitol, titanium dioxide, water

Questions or comments? 1-888-333-9792

PRINCIPAL DISPLAY PANEL

SLEEP AID

Diphenhydramine HCl 50 mg 100 Softgels



MAXIMUM STRENGTH SLEEP AID

diphenhydramine hcl capsule, gelatin coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-4099
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;903	
Contains				

P	Packaging					
#	tem Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:68210- 4099-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	07/02/2020			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M010	07/02/2020	

Labeler - SPIRIT PHARMACEUTICALS LLC (179621011)

Revised: 12/2023 SPIRIT PHARMACEUTICALS LLC