

NIGHTTIME SLEEP AID- diphenhydramine hydrochloride capsule, liquid filled
Shield Pharmaceuticals Corp

Nighttime Sleep Aid

Drug Facts

Active ingredient (in each softgel)

Diphenhydramine HCl 50 mg

Purpose

Nighttime sleep-aid

Uses

- for 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

Stop use and ask a doctor if

sleeplessness persist 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 (1-800-222-1222) right away.

Directions

- adults and children 12 years of age and over: 1 softgel (50 mg) at bedtime if needed, or as directed by a doctor

Other information

- store at controlled room temperature 20-25°C (68-77°F)
- protect from light, heat and moisture

Inactive ingredients

FD&C Blue #1, gelatin, glycerine, polyethylene glycol 400, propylene glycol, sorbitan

Questions or comments?

1-800-373-6981

Distributed by:

Shield Pharmaceuticals Corp.

Hauppauge, NY 11788

PRINCIPAL DISPLAY PANEL

Compare to the active ingredient in Unisom® SleepGels

Sleep-Aid

Diphenhydramine HCl Softgels, 50 mg

Carton



NIGHTTIME SLEEP AID

diphenhydramine hydrochloride capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83059-0028
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)	
SORBITAN (UNII: 6O92ICV9RU)	

Product Characteristics

Color	blue	Score	no score
Shape	CAPSULE	Size	13mm
Flavor		Imprint Code	SD28
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83059-0028-8	1 in 1 CARTON	04/08/2024	
1		8 in 1 BOTTLE; 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	04/08/2024	

Labeler - Shield Pharmaceuticals Corp (118724924)

Revised: 4/2024

Shield Pharmaceuticals Corp