

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, glycerin, polyethylene glycol, propylene glycol, purified water, sorbitol sorbitan, titanium dioxide

Questions or comments?

1-800-373-6981

Distributed by:

Shield Pharmaceuticals Corp.

Ronkonkoma, NY 11779


PRINCIPAL DISPLAY PANEL

Compare to the active ingredient in Unisom® SleepGels

Sleep-Aid

Diphenhydramine HCl Softgels, 50 mg

Label



Compare to the active ingredient in Unisom® SleepGels®†

Nighttime Sleep-Aid

Diphenhydramine HCl Softgels, 50 mg

60 softgels


TAMPER EVIDENT: DO NOT USE IF SAFETY SEAL UNDER THE CAP IS BROKEN OR MISSING

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Drug Facts (continued under the label)

Distributed by:
Shield Pharmaceuticals Corp.
Ronkonkoma, NY 11779



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LOT: EXP.:

Made in India
QRG 11/25



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<small>This product is not manufactured or distributed by Chattem, Inc., owner of the registered trademark Unisome.</small>

NIGHTTIME SLEEP AID

diphenhydramine hydrochloride capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83059-0122
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)			
SORBITAN (UNII: 6O92ICV9RU)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
Product Characteristics			
Color	blue	Score	no score
Shape	CAPSULE	Size	13mm
Flavor		Imprint Code	SDU
Contains			
Packaging			

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83059-0122-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	12/05/2027	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug		M010	12/05/2025	

Labeler - Shield Pharmaceuticals Corp (118724924)

Revised: 12/2025

Shield Pharmaceuticals Corp