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

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 ifsleeplessness 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

- do not take more than directed
- take only one dose per day (24 hours)

adults & children 12 yrs & take 2 capsules at bedtime if needed or as directed by a over 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 no. 1, FD&C red no. 40, gelatin, glycerin, methylparaben*, polyethylene glycol-400, povidone, propylene glycol, propylparaben*, purified water, sorbitol sorbitan solution. *may contain this inactive ingredient

Questions or comments?

1-800-373-6981

Distributed by:

Shield Pharmaceuticals Corp.

Ronkonkoma, NY 11779

Sleep Aid

Diphenhydramine HCl 25 mg

Fall Asleep Fast

- Non-Habit Forming
- Not for treating Pain, Cold or Flu
- Just for Sleep

Carton



KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

DO NOT USE IF PACKAGE IS OPENED ON IF BLISTER BROKEN OR SHOWS ANY SIGNS OF TAMPERING

TAMPER EVIDENT: D UNIT IS TORN, B

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SLEEP AID

diphenhydramine hydrochloride capsule, liquid filled

Product Information Product Type HUMAN OTC DRUG **Item Code (Source)** NDC:83059-0115 **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)		
METHYLPARABEN (UNII: A2I8C7HI9T)		

POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLPARABEN (UNII: Z8IX2SC10H)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
SORBITAN (UNII: 6092ICV9RU)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color	purple	Score	no score
Shape	CAPSULE (OBLONG)	Size	15mm
Flavor		Imprint Code	SD13;SDS
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:83059- 0115-8	1 in 1 CARTON	11/12/2025	
1	8 in 1 BLISTER PACK; 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	11/12/2025	

Labeler - Shield Pharmaceuticals Corp (118724924)

Revised: 11/2025 Shield Pharmaceuticals Corp