

SLEEPAID (DIPHENHYDRAMINE HCL)- diphenhydramine hcl capsule, liquid filled
APNAR PHARMA LP

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

SleepAid (Diphenhydramine Hydrochloride 50mg Capsule,Liquid Filled)

DRUG FACTS

Active ingredient (in each soft gel)

Diphenhydramine HCL 50 mg

Purpose

Nighttime sleep-aid

USES

Use for relief of occasional sleeplessness.

Warnings

Do not use

- for children under 12 years of age
- with any other products 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 persists continuously for more than 2 weeks. Insomnia may be a symptom of a serious underlying medical illness.

If pregnant or breast-feeding,

ask a health professional before use.

KEEP OUT OF THE 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: Take 1 softgel (50 mg) at bedtime if needed, or as directed by a doctor

Other information

- store at room temperature 15° to 30° C (59° to 86° F)
- avoid excessive heat
- do not use if imprinted safety seal under cap is broken or missing

Inactive Ingredients

FD&C blue #1, gelatin, glycerin, polyethylene glycol, purified water, sorbitol sorbitan solution, white ink

Questions or comments?

- Call 1-855-642-2594

*Compare to active ingredient in Unisom[®] SleepGels[®]

*This product is not manufactured or distributed by Chattem, Inc., owner of the registered trademark Unisom[®]

Rev.: 03/2023

Manufactured by:

Apnar Pharma LLP

East Windsor, NJ 08520

NDC 24689-154-01

SleepAid

Diphenhydramine HCL 50 mg

- Safe, non habit-forming
- One softgel per dose

Made in USA

100 Soft gels

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Rev.: 03/2023

Lot #: _____
Exp date: _____

Unvarnished Area
1.5 x 0.5 Inches

SLEEPAID (DIPHENHYDRAMINE HCL)

diphenhydramine hcl capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24689-154
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)	
GLYCERIN (UNII: PDC6A3C0OX)	
GELATIN (UNII: 2G86QN327L)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SORBITAN (UNII: 6O92ICV9RU)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	blue	Score	no score
Shape	OVAL	Size	13mm
Flavor		Imprint Code	AD1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24689-154-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/04/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M010	05/04/2023	

Labeler - APNAR PHARMA LP (079568229)

Establishment

Name	Address	ID/FEI	Business Operations
APNAR PHARMA LLP		118530917	manufacture(24689-154) , analysis(24689-154) , pack(24689-154)

Revised: 5/2023

APNAR PHARMA LP