#### 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.

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## 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<sup>o</sup> to 30<sup>o</sup> C (59<sup>o</sup> to 86<sup>o</sup> 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  $^{\ensuremath{\mathbb{R}}}$  SleepGels  $^{\ensuremath{\mathbb{R}}}$ 

\*This product is not manufactured or distributed by Chattem, Inc., owner of the registered trademark Unisom  $^{\ensuremath{\mathbb{R}}}$ 

Rev.: 03/2023

Manufactured by:

## Apnar Pharma LLP

East Windsor, NJ 08520

## NDC 24689-154-01

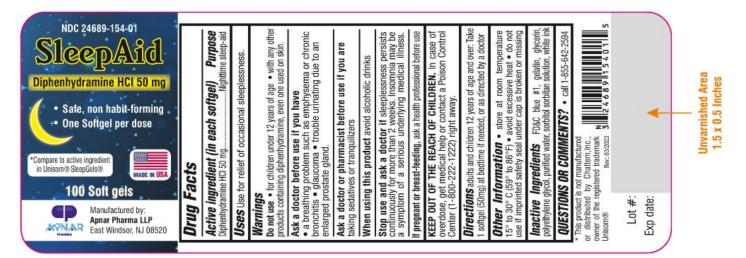
## SleepAid

Diphenhydramine HCL 50 mg

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

Made in USA

# 100 Soft gels



SLEEPAID (DIPHENHYDRAMINE HCL) diphenhydramine hcl capsule, liquid filled								
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Product Inform	nation							
Product Type		HUMAN OTC DRUG	Item Cod	Item Code (Source) NDC		C:24689-154		
Route of Adminis	stration	ORAL						
Route of Adminis								
Active Ingredie	ent/Active	Moiety						
Ingredient Name Basis of Streng						Strengt		
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) DIPHENHYDRAMINE   (DIPHENHYDRAMINE - UNII:8GTS82S83M) HYDROCHLORIDE						50 mg		
Inactive Ingree	dients							
		Ingredient Name	e		S	trength		
FD&C BLUE NO. 1	(UNII: H3R47K3	-						
GLYCERIN (UNII: PDC6A3C0OX)								
GELATIN (UNII: 2G8	6QN327L)							
POLYETHYLENE GL	YCOL, UNSP	ECIFIED (UNII: 3WJQ0SDV	V1A)					
SORBITAN (UNII: 6092ICV9RU)								
WATER (UNII: 059QF0K00R)								
SORBITOL (UNII: 506T60A25R)								
Product Chara	ctoristics							
		LO Coore			no score			
					I3mm			
-	Shape OVAL Siz							
Flavor		Imprint C	.ode	F	AD1			
Contains								
Packaging								
# Item Code	Pa	Package Description		arketing Start Date	-			
NDC:24689-154-     100 in 1 BOTTLE; Type 0: Not a Combination     05/04/2023								
Marketing I	nformat	ion						
Marketing I Marketing Category		<b>ion</b> tion Number or Mon Citation	ograph	Marketing Start Date		eting End Date		

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

Revised: 5/2023

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