

**SLEEPAID SOFTGELS- diphenhydramine hydrochloride capsule, liquid filled  
PIONEER LIFE SCIENCES, LLC**

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**SleepAid Softgels Diphenhydramine HCl 50 mg**

**Active Ingredient (In Each Softgel)**

Diphenhydramine HCl 50 mg

**Purpose**

Nighttime sleep-aid

**Uses**

for relief of occasional sleeplessness

***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.

**Stop use and ask a doctor if** sleeplessness 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.** In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

***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 between 15-30°C (59-86°F). Avoid high humidity. Protect from light.

## Inactive Ingredients:

Polyethylene Glycol, Gelatin, Sorbitol, Sorbitan Anhydrous, Glycerin, Brilliant Blue FCF.

## Questions Or Comments?

Call toll-free 1 (732) 689-5070 Monday through Friday 9 am to 5 pm EST.

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

Distributed by: Gencare Consumer Products, LLC  
40E Cotters Ln, Suite A, East Brunswick, NJ 08816

## NDC 72090-023-02 (96 Softgels t in HDPE Bottle)



**Maximum Strength**  
†compares to UNISOM® SLEEPGELS® active ingredients.  
**GenCare**  
 generic healthcare  
**SleepAid Softgels**  
 Diphenhydramine HCl 50 mg  
 Safe | Non-Habit Forming  
 Fall Asleep Fast  
 Sleep Soundly  
 Wake Refreshed  
**96 softgels**  
1 soft gel per dose not actual size

**TAMPER EVIDENT** Do not use if safety seal under cap is broken or missing.

<b>Drug Facts</b>	<b>Purpose</b> Nighttime sleep-aid
<b>Active Ingredient (in Each Softgel)</b> Diphenhydramine HCl 50 mg	
<b>Uses:</b> for relief of occasional sleeplessness	
<b>Do not use:</b> for children under 12 years of age with any other product containing diphenhydramine, even one used on skin.	
<b>Ask a doctor before use if you have</b> a breathing problem such as emphysema or chronic bronchitis ■ glaucoma ■ trouble urinating due to an enlarged prostate gland.	
<b>Ask a doctor or pharmacist before use if you are taking</b> sedatives or tranquilizers.	
<b>When using this product avoid</b> alcoholic drinks	
<b>Stop use and ask a doctor if</b> sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of serious underlying medical illness.	
<b>If pregnant or breast-feeding, ask a health professional before use. KEEP OUT OF REACH OF CHILDREN.</b> In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)	
<b>Directions:</b> Adults and children 12 years of age and over: 1 softgel (50 mg) at bedtime if needed, or as directed by a doctor.	
<b>Other information:</b> store between 15-30°C (59-86°F). Avoid high humidity. Protect from light.	
<b>Inactive Ingredients:</b> Polyethylene Glycol, Gelatin, Sorbitol, Sorbitan Anhydrous, Glycerin, Brilliant Blue FCF.	
<b>Questions or Comments?</b> Call toll-free 1 (732) 689-5070 Monday through Friday 9 am to 5 pm EST. or go to: www.gencare.health	

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**PLD166-00**

Lot No. \_\_\_\_\_  
Exp. Dt. \_\_\_\_\_

Maximum Strength Nighttime Sleep Aid (96 Softgels) NDC

## SLEEP AID SOFTGELS

diphenhydramine hydrochloride capsule, liquid filled

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72090-023
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	50 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SORBITAN</b> (UNII: 6O92ICV9RU)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	

## Product Characteristics

<b>Color</b>	blue	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	15mm
<b>Flavor</b>		<b>Imprint Code</b>	cp71
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72090-023-02	96 in 1 BOTTLE; Type 0: Not a Combination Product	04/25/2024	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M010	04/25/2024	

**Labeler** - PIONEER LIFE SCIENCES, LLC (014092742)

Revised: 4/2024

PIONEER LIFE SCIENCES, LLC