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

SleepAid Softgels Diphenhydramine HCI 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 72090-023-01 (180 Sofgels t in HDPE Bottle)



SLEEPAID SOFTGELS diphenhydramine hydrochloride capsule, liquid filled Product Information Product Type HUMAN OTC DRUG Route of Administration ORAL Active Ingredient/Active Woiety

Ingredient Name			Basis of S	Strength	Strength	
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: (DIPHENHYDRAMINE - UNII:8GTS82S83M)		I: TC2D6JAD40)	DIPHENHYDRAMINE HYDROCHLORIDE		50 mg	
Inactive Ingred	ients					
Ingredient Name					Strength	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)						
GELATIN (UNII: 2G860	QN327L)					
SORBITOL (UNII: 506T60A25R)						
SORBITAN (UNII: 6092ICV9RU)						
GLYCERIN (UNII: PDC6A3C0OX)						
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)						
Product Charac	teristics					
Color	blue	blue Score			no score	
Shape	OVAL	Size		15mm		
Flavor		Imprint Code		cp71		
Contains						
Packaging						
# Item Code	Package Description		Marketing Start Date	Marketing End Date		
	180 in 1 BOTTLE; Type 0: Not a Combination Product		04/25/2024			
Marketing Ir	formation					
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	-		
OTC Monograph Drug	M010		04/25/2024			
51 5						

Labeler - PIONEER LIFE SCIENCES, LLC (014092742)

Revised: 4/2024

PIONEER LIFE SCIENCES, LLC