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.

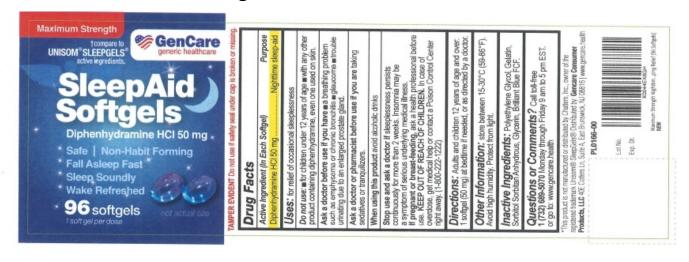
Questions Or Comments?

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 72090-023-02 (96 Sofgels t in HDPE Bottle)



SLEEPAID SOFTGELS

diphenhydramine hydrochloride capsule, liquid filled

Product Information	roduct Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72090-023	
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		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
GELATIN (UNII: 2G86QN327L)			
SORBITOL (UNII: 506T60A25R)			
SORBITAN (UNII: 6O92ICV9RU)			
GLYCERIN (UNII: PDC6A3C0OX)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			

Product Characteristics			
Color	blue	Score	no score
Shape	OVAL	Size	15mm
Flavor		Imprint Code	cp71
Contains			

ı	P	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