

SLEEP AID NIGHTTIME- diphenhydramine hcl capsule

Sam's West, Inc

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.

Drug Facts

Active ingredient (in each softgel)

Diphenhydramine HCl 50 mg

Purpose

Nighttime sleep-aid

Uses

For relief of occasional sleeplessness.

Warnings

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.

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 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 older: 1 softgel (50 mg) at bedtime if needed, or as directed by a doctor

Other information

- store between 15-30°C (59-86°F)

Inactive ingredients

FD&C blue #1, gelatin, glycerin, lecithin, light mineral oil, mannitol, polyethylene glycol, purified water, sorbitan, sorbitol, white ink

Questions or comments?

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

Principal Display Panel

Compare to Unisom® SleepGels® active ingredient**
maximum strength

Sleep-Aid

diphenhydramine HCl 50 mg

nighttime sleep-aid

safe, non habit-forming

- Fall asleep fast
- Sleep soundly/wake up refreshed

Softgels

**This product is not manufactured or distributed by Chattem, Inc., distributor of Unisom® SleepGels®.

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

DISTRIBUTED BY

Product Label



diphenhydramine hcl capsule

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68196-916
Route of Administration	ORAL		

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)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
MANNITOL (UNII: 3OWL53L36A)	

Product Characteristics

Color	blue	Score	no score
Shape	CAPSULE	Size	13mm
Flavor		Imprint Code	PC5
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68196-916-92	2 in 1 PACKAGE	04/01/2020	04/01/2025
1		96 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part338	04/01/2020	04/01/2025

Labeler - Sam's West, Inc (051957769)

Revised: 11/2022

Sam's West, Inc