

**NIGHTTIME SLEEP AID- diphenhydramine hcl 50mg capsule, liquid filled
PuraCap Pharmaceutical LLC**

Diphenhydramine HCl 50mg

Drug Facts

Active ingredient (in each softgel)

Diphenhydramine HCl 50 mg

Purpose

Nighttime sleep-aid

Use

- for the 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 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 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.

Directions

- adults and children 12 years of age and over:

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

Other information

- store at room temperature 15°-30° C (59°-86° F)

Inactive ingredients

FD&C blue #1, gelatin, glycerin, polyethylene glycol, purified water, sorbitol sorbitan solution and white edible ink

Questions or comments?

Call toll free: **1-855-215-8180**

PRINCIPAL DISPLAY PANEL

Nighttime SLEEP-AID 100 Softgels

Diphenhydramine HCl 50mg

compare to active ingredient in Unisom® SleepGels® SoftGels

NDC 51013-817-01

| |
|---|
| <p>Drug Facts (continued)</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p> |
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†This product is not manufactured or distributed by Chatterm, Inc., owner of the registered trademark Unisom® SleepGels® SoftGels.

100 SOFTGELS

Nighttime

Sleep-Aid

Diphenhydramine HCl

50 mg

Compare to Active Ingredient in Unisom® SleepGels® SoftGels

DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

| | |
|--|---------------------|
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PuraVation® NDC 51013-817-01

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PC11-00

Drug Facts (continued under label)

Distributed by: PuraCap
Pharmaceutical LLC
Bridgewater, NJ 08807

Made in China



Lot No.:

Exp. Date:

NIGHTTIME SLEEP AID

diphenhydramine hcl 50mg capsule, liquid filled

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:51013-817 |
| 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 |
|--|----------|
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| GELATIN (UNII: 2G86QN327L) | |
| SORBITOL (UNII: 506T60A25R) | |
| WATER (UNII: 059QF0KO0R) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |

Product Characteristics

| | | | |
|-----------------|-------------------|---------------------|----------|
| Color | blue (clear blue) | Score | no score |
| Shape | OVAL | Size | 13mm |
| Flavor | | Imprint Code | PC5 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:51013-817-01 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 11/30/2024 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M010 | 11/30/2024 | |

Labeler - PuraCap Pharmaceutical LLC (962106329)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---------|-----------|------------------------|
| Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd | | 421293287 | manufacture(51013-817) |

Revised: 11/2024

PuraCap Pharmaceutical LLC