

**NIGHTTIME SLEEP AID- diphenhydramine hydrochloride capsule, liquid filled
SPIRIT PHARMACEUTICALS LLC**

NIGHTTIME SLEEP-AID

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 persist 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

Inactive ingredients

FD&C Blue#1, gelatin, glycerin, polyethylene glycol-400, propylene glycol, sorbitol, titanium dioxide, water

Questions or comments?

1-888-333-9792

PRINCIPAL DISPLAY PANEL

Maximum Strength

Nighttime Sleep-aid

Diphenhydramine HCl 50 mg - Nighttime Sleep-Aid

Helps reduce difficulty falling asleep

Non-habit forming

8 Softgels



NIGHTTIME SLEEP AID

diphenhydramine hydrochloride capsule, liquid filled

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:68210-4147 |
| 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) | |
| GELATIN (UNII: 2G86QN327L) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| SORBITOL (UNII: 506T60A25R) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| WATER (UNII: 059QF0KO0R) | |

Product Characteristics

| | | | |
|-----------------|------|---------------------|----------|
| Color | blue | Score | no score |
| Shape | OVAL | Size | 13mm |
| Flavor | | Imprint Code | 206;903 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:68210-4147-8 | 1 in 1 CARTON | 04/28/2021 | |
| 1 | | 8 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M010 | 04/28/2021 | |

