

SLEEP AID- diphenhydramine hcl tablet, film coated
Cardinal Health 110, LLC. DBA Leader

Leader 44-367

Active ingredient (in each caplet)

Diphenhydramine HCl 25 mg

Purpose

Nighttime sleep-aid

Uses

- for relief of occasional sleeplessness
- reduces time to fall asleep if you have difficulty falling asleep

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
- difficulty in urination due to enlargement of the prostate gland
- glaucoma

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers.

When using this product

avoid alcoholic beverages.

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 right away.

Directions

- **do not take more than directed**
- adults and children 12 years and over: take 2 caplets at bedtime if needed or as directed by a doctor
- children under 12 years: do not use

Other information

- **each caplet contains:** calcium 30 mg
- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- protect from moisture
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

Inactive ingredients

corn starch, dibasic calcium phosphate dihydrate, FD&C blue #1 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, silicon dioxide, stearic acid, talc, titanium dioxide

Questions or comments?

1-800-426-9391

Principal Display Panel

NDC 70000-0244-1

LEADER™

Sleep-Aid

Diphenhydramine HCl, 25 mg
Nighttime Sleep-Aid

Non-Habit Forming
Not for Treating Pain,
Cold or Flu

24 CAPLETS

Actual Size

**COMPARE TO
SIMPLY SLEEP®
NIGHTTIME SLEEP AID**
active ingredient*

100% Money Back Guarantee

**TAMPER EVIDENT: DO NOT USE IF
PACKAGE IS OPENED OR IF BLISTER
UNIT IS TORN, BROKEN OR SHOWS
ANY SIGNS OF TAMPERING**

✓All LEADER™ Brand Products Have A
100% Money Back Guarantee
Return to place of purchase if not satisfied.

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DUBLIN, OHIO 43017

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Essential to Care™ since 1979

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*This product is not manufactured or distributed by Johnson &
Johnson Corporation, owner of the registered trademark Simply
Sleep® Nighttime Sleep Aid. 50844 REV1019A36708

LEADER²

Sleep-Aid

Diphenhydramine HCl, 25 mg | Nighttime Sleep-Aid

LEADER²

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B-0225-367-08-RR
REV1019A36708

CIN 5312053 REV. 2/21



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Leader 44-367

SLEEP AID

diphenhydramine hcl tablet, film coated

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:70000-0244 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|----------------------------------|----------|
| DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M) | DIPHENHYDRAMINE HYDROCHLORIDE | 25 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| STARCH, CORN (UNII: O8232NY3SJ) | |
| DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP) | |
| FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| TALC (UNII: 7SEV7J4R1U) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |

Product Characteristics

| | | | |
|-----------------|------|---------------------|----------|
| Color | blue | Score | no score |
| Shape | OVAL | Size | 11mm |
| Flavor | | Imprint Code | 44;367 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:70000-0244-1 | 2 in 1 CARTON | 06/10/2000 | |
| 1 | | 12 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 | 06/10/2000 | |

Labeler - Cardinal Health 110, LLC. DBA Leader (063997360)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|---------------------|
| LNK International, Inc. | | 038154464 | pack(70000-0244) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|--|
| LNK International, Inc. | | 832867837 | manufacture(70000-0244) , pack(70000-0244) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|-------------------------|
| LNK International, Inc. | | 832867894 | manufacture(70000-0244) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|-------------------------|
| LNK International, Inc. | | 868734088 | manufacture(70000-0244) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|---------------------|
| LNK International, Inc. | | 967626305 | pack(70000-0244) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|-------------------------|
| LNK International, Inc. | | 117025878 | manufacture(70000-0244) |

Revised: 3/2025

Cardinal Health 110, LLC. DBA Leader