

**LEADER SLEEP AID- diphenhydramine hydrochloride tablet, film coated  
Cardinal Health 110, LLC. dba Leader**

*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.*

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**Cardinal Health Sleep Aid Drug Facts**

**Active ingredient (in each caplet)**

Diphenhydramine HCl 25 mg

**Purpose**

Nighttime sleep-aid

**Uses**

for relief of occasional sleeplessness

**Warnings**

**Do not use**

- in 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
- trouble urinating due to an enlarged prostate gland
- glaucoma

**Ask a doctor or pharmacist before use if you are**

taking sedatives or tranquilizers

**When using this product**

- avoid alcoholic drinks
- drowsiness may occur
- do not drive a motor vehicle or operate machinery

**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.**

**Overdose warning:** 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 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 15 mg
- store at 20-25°C (68-77°F). Avoid high humidity. Protect from light.
- **do not use if blister unit is broken or torn**

**Inactive ingredients**

carnauba wax, crospovidone, dibasic calcium phosphate dihydrate, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, pregelatinized starch, stearic acid, titanium dioxide

**Questions or comments?**

**1-800-719-9260**

**Principal Display Panel**

Sleep Aid

Diphenhydramine HCl, 25 mg

Nighttime Sleep Aid

Non Habit-Forming

Helps You Fall Asleep

Does Not Contain Pain Reliever

COMPARE TO SIMPLY SLEEP® NIGHTTIME SLEEP AID active ingredient

100% Money Back Guarantee

24 CAPLETS

Actual Size



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

**LEADER**™

NDC 70000-0467-1

# Sleep Aid

Diphenhydramine HCl, 25 mg  
Nighttime Sleep Aid

Non Habit-Forming  
Helps You Fall Asleep  
Does Not Contain Pain Reliever

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NDC 70000-0467-1

### Drug Facts

| Active ingredient<br>(in each caplet) | Purpose             |
|---------------------------------------|---------------------|
| Diphenhydramine HCl 25 mg.....        | Nighttime sleep-aid |

**Use** for relief of occasional sleeplessness

### Warnings

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- a breathing problems such as emphysema or chronic bronchitis
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### Drug Facts (continued)

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**Questions or comments? 1-800-719-9260**

### Gluten Free

\*This product is not manufactured or distributed by

professional before use.

Johnson & Johnson, owner of the registered trademark  
Simply Sleep®.

CIN 5493234 REV. 1/19



## LEADER SLEEP AID

diphenhydramine hydrochloride tablet, film coated

### Product Information

|                                |                |                           |                |
|--------------------------------|----------------|---------------------------|----------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:70000-0467 |
| <b>Route of Administration</b> | ORAL           |                           |                |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength                | Strength |
|--|----------------------------------|----------|
| <b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40)<br>(DIPHENHYDRAMINE - UNII:8GTS82S83M) | DIPHENHYDRAMINE<br>HYDROCHLORIDE | 25 mg    |

### Inactive Ingredients

| Ingredient Name   | Strength |
|---|----------|
| <b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)                        |          |
| <b>CROSPVIDONE (15 MPAS AT 5%)</b> (UNII: 68401960MK)         |          |
| <b>DIBASIC CALCIUM PHOSPHATE DIHYDRATE</b> (UNII: O7TSZ97GEP) |          |
| <b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)                 |          |
| <b>FD&amp;C BLUE NO. 2</b> (UNII: L06K8R7DQK)                 |          |
| <b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)           |          |
| <b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)                  |          |
| <b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)          |          |
| <b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)    |          |
| <b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)                      |          |
| <b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)                        |          |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)                    |          |

### Product Characteristics

|                 |                   |                     |          |
|-----------------|-------------------|---------------------|----------|
| <b>Color</b>    | BLUE (Light Blue) | <b>Score</b>        | no score |
| <b>Shape</b>    | OVAL              | <b>Size</b>         | 11mm     |
| <b>Flavor</b>   |                   | <b>Imprint Code</b> | L431     |
| <b>Contains</b> |                   |                     |          |

### Packaging

Marketing Start      Marketing End

| # | Item Code        | Package Description                                    | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:70000-0467-1 | 12 in 1 CARTON   | 02/25/2019           |                    |
| 1 |                  | 2 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 final | part338                                  | 02/25/2019           |                    |

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

Revised: 6/2021

Cardinal Health 110, LLC. dba Leader