

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.

DISTRIBUTED BY CARDINAL HEALTH
DUBLIN, OHIO 43017

www.myleader.com 1-800-200-6313
Essential to Care™ since 1979

© 2021 Cardinal Health. All Rights Reserved.
CARDINAL HEALTH, the Cardinal Health LOGO,
ESSENTIAL TO CARE, LEADER, and the Leader LOGO
are trademarks or registered trademarks of
Cardinal Health. All other marks are the property
of their respective owners.

*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

LEADER²

NDC 70000-0244-1

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

Sleep-Aid

Diphenhydramine HCl, 25 mg | Nighttime Sleep-Aid

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

Return to place of purchase if not satisfied.

✓ All LEADER²™ Brand Products Have A
100% Money Back Guarantee

OMIT A



B-0225-367-08-RR
REV1019A36708

CIN 5312053 REV. 2/21



CardinalHealth™

DISTRIBUTED BY CARDINAL HEALTH
DUBLIN, OHIO 43017
www.myleader.com 1-800-200-6313
Essential to Care™ since 1979

©2021 Cardinal Health. All Rights Reserved.
CARDINAL HEALTH, the Cardinal Health LOGO,
ESSENTIAL TO CARE, LEADER, and the Leader LOGO
are trademarks or registered trademarks of
Cardinal Health. All other marks are the property
of their respective owners.

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

Questions or comments? 1-800-426-9391

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

- see end flap for expiration date and lot number
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- protect from moisture

Other information
■ each caplet contains: calcium 30 mg
■ TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN

- 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

Diphenhydramine HCl 25 mg 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
■ a breathing problem such as emphysema or chronic bronchitis ■ glaucoma
■ difficulty in urination due to enlargement of the prostate gland

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.



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: 3/2024

Cardinal Health 110, LLC. DBA Leader