NIGHTTIME SLEEP AID- diphenhydramine hydrochloride tablet, film coated H E B

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.

HEB Nighttime Sleep Aid Drug Facts

Active ingredient (in each caplet)

Diphenhydramine HCl 25 mg

Purpose

Nighttime sleep-aid

Use

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
- 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
- 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 | take 2 caplets at bedtime if needed, or as directed by a |
|-------------------------|--|
| years and over | 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

Compare to Simply Sleep ${}^{\circledR}$ Nighttime Sleep Aid Caplets active ingredient

Nighttime Sleep-Aid

Diphenhydramine HCl 25 mg

Helps You Fall Asleep

Safe, Non-Habit Forming

Does Not Contain Pain Reliever

actual size

24 MINI-CAPLETS



Nighttime Sleep-Aid

Diphenhydramine HCI, 25 mg

Compare to Simply Sleep* Nighttime Sleep Aid Capiets active ingredient*

NDC 37808-431-62



Nighttime Sleep-Aid

Diphenhydramine HCI 25 mg

Helps You Fall Asleep

- Safe, Non-Habit Forming
- Does Not Contain Pain Reliever

24 MINI-CAPLETS

Drug Facts

Active ingredient Purpose (in each caplet)

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Drug Facts (continued)

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Questions or comments? 1-800-719-9260

*This product is not manufactured or distributed by McNeil Consumer Heal Incare, distributor of Simply Sleep® Nighttime Sleep Aid Caplets.

GLUTEN FREE



NIGHTTIME SLEEP AID

diphenhydramine hydrochloride tablet, film coated

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:37808-431

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name
Basis of Strength
DIPHENHYDRAMINE HYDRO CHLO RIDE (UNII: TC2D6 JAD40) (DIPHENHYDRAMINE - UNII:8 GTS8 2S8 3M)
DIPHENHYDRAMINE HYDRO CHLO RIDE

25 mg

| Inactive Ingredients | | |
|---|----------|--|
| Ingredient Name | Strength | |
| CARNAUBA WAX (UNII: R12CBM0 EIZ) | | |
| CROSPO VIDO NE (15 MPA.S AT 5%) (UNII: 68401960 MK) | | |
| DIBASIC CALCIUM PHO SPHATE DIHYDRATE (UNII: O7TSZ97GEP) | | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | | |
| FD&C BLUE NO. 2 (UNII: L06K8R7DQK) | | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | | |
| MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U) | | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | | |
| POLYSORBATE 80 (UNII: 6 OZP39 ZG8 H) | | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | | |
| TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) | | |

| Product Characteristics | | | |
|-------------------------|-------------------|--------------|----------|
| Color | BLUE (Light Blue) | Score | no score |
| Shape | OVAL | Size | 11mm |
| Flavor | | Imprint Code | L431 |
| Contains | | | |

| Packaging | | | |
|--------------------|---------------------|-----------------------------|---------------------------|
| # Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 NDC:37808-431-62 | 12 in 1 CARTON | 10/09/2009 | |

| 1 | 2 in 1 BLISTER PACK; Type 0: Not a Combination Produc | t | |
|-----------------------|---|----------------------|--------------------|
| | | | |
| | | | |
| Marketing Information | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph final | part338 | 10/09/2009 | |
| | | | |

Labeler - HEB (007924756)

Revised: 12/2019 HE B