SLEEP-AID- diphenhydramine hcl tablet, chewable Rite Aid Corporation

Rite Aid 44-685

Active ingredient (in each chewable tablet)

Diphenhydramine HCl 25 mg

Purpose

Nighttime sleep-aid

Uses

- reduces time to fall asleep if you have difficulty falling asleep
- 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
- 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.

Directions

- do not take more than directed
- chew or crush tablets completely before swallowing; do not swallow tablets whole
- take only one dose per day (24 hours)
- adults and children 12 years and over: 2 chewable tablets at bedtime if needed, or as directed by a doctor
- children under 12 years: do not use

Other information

- TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- avoid high humidity
- see end flap for expiration date and lot number

Inactive ingredients

D&C red #27 aluminum lake, D&C red #30 aluminum lake, dextrates hydrated, ethylcellulose, FD&C blue #1 aluminum lake, flavor, hydroxypropyl cellulose, magnesium stearate, mannitol, stearic acid, sucralose, sucrose

Questions or comments?

1-800-426-9391

Principal display panel

FREE FROM CAFFEINE FREE

Compare to the active ingredient in Unisom® Chewables*

NDC 11822-0685-8

SLEEP-AID

DIPHENHYDRAMINE HCI, 25 mg CHEWABLE TABLETS nighttime sleep-aid non-habit forming not for treating pain, cold or flu

ACTUAL SIZE

Chew or crush tablets completely before swallowing.

ACTUAL SIZE

24

TABLETS

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

*This product is not manufactured or distributed by Chattem, Inc., owner of the registered trademark Unisom® Chewables. ORG011968508

DISTRIBUTED BY:

RITE AID, 30 HUNTER LANE, CAMP HILL, PA 17011 www.riteaid.com

SATISFACTION GUARANTEE

If you're not satisfied, we'll happily refund your money.





FREE **CAFFEINE FREE** FREM

Compare to the active ingredient in Unisom® Chewables*

NDC 11822-0685-8

OR IF BLISTE TAMPERING

USE

6

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print / no varnish area

9

lot no & exp date

EEP-A

DIPHENHYDRAMINE HCI, 25 mg

CHEWABLE TABLETS

nighttime sleep-aid

non-habit forming not for treating pain, cold or flu

TABLETS

ACTUAL SIZE

moo.bisesin.www **DISTRIBUTED BY:** RITE AID, 30 HUNTER LANE, CAMP HILL, PA 17011

ORG011968508 44808 *This product is not manufactured or distributed by Chattem, Inc., owner of the registered trademark Unisom® Chewables.

tablets completely before swallowing. If you're not satisfied, we'll happily refund your money.

GUARANTEE SATISFACTION

B-1702-685-08-R2 0RG011968508

mannitol, stearic acid, sucralose, sucrose hydroxypropyl cellulose, magnesium stearate, ethylcellulose, FD&C blue #1 aluminum lake, flavor, lake, D&C red #30 aluminum lake, dextrates hydrated,

Chew or crush

- IS OPENED OR BLISTER IS TORN OR BROKEN
- TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE Other information
- DIYECTIONS

 a do not take more than directed

Keep out of reach of children. In case of overdose, get

a symptom of a serious underlying medical illness. continuously for more than 2 weeks. Insomnia may be Stop use and ask a doctor if sleeplessness persists When using this product avoid alcoholic beverages. taking sedatives or tranquilizers. Ask a doctor or pharmacist before use if you are prostate gland ■ difficulty in urination due to enlargement of the a breathing problem such as emphysema or chronic Ask a doctor before use if you have ■ children under 12 years: do not use even one used on skin doctor lacktriangle with any other product containing diphenhydramine, ■ for children under 12 years of age Do not use ■ take only one dose per day (24 hours) Warnings do not swallow tablets whole asleep a for relief of occasional sleeplessness ■ reduces time to fall asleep if you have difficulty falling Nighttime sleep-aid Diphenhydramine HCI 25 mg. (in each chewable tablet)

Inactive ingredients D&C red #27 aluminum see end flap for expiration date and lot number ■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F) ■ avoid high humidity tablets at bedtime if needed, or as directed by a ■ adults and children 12 years and over: 2 chewable chew or crush tablets completely before swallowing; medical help or contact a Poison Control Center right professional before use. Purpose Active ingredient If pregnant or breast-feeding, ask a health Drug Facts (continued)

Questions or comments? 1-800-426-9391 Drug Facts (continued)

Drug Facts

SLEEP-AID

diphenhydramine hcl tablet, chewable

| Product Information | | | | |
|-------------------------|----------------|--------------------|----------------|--|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:11822-0685 | |
| 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 |
| D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX) | |
| D&C RED NO. 30 (UNII: 2S42T2808B) | |
| DEXTROSE MONOHYDRATE (UNII: LX22YL083G) | |
| ETHYLCELLULOSE, UNSPECIFIED (UNII: 7Z8S9VYZ4B) | |
| FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM) | |
| HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| MANNITOL (UNII: 30WL53L36A) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | |
| SUCROSE (UNII: C151H8M554) | |

| Product Characteristics | | | | |
|-------------------------|--------|--------------|----------|--|
| Color | purple | Score | no score | |
| Shape | ROUND | Size | 13mm | |
| Flavor | GRAPE | Imprint Code | 44;685 | |
| Contains | | | | |

| P | Packaging | | | | |
|---|----------------------|--|-------------------------|-----------------------|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| 1 | NDC:11822- 0685-8 | 4 in 1 CARTON | 06/16/2021 | | |
| 1 | | 6 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 | 06/16/2021 | |
| | | | |

Labeler - Rite Aid Corporation (014578892)

| Establishment | | | |
|-------------------------|---------|-----------|----------------------------|
| Name | Address | ID/FEI | Business Operations |
| LNK International, Inc. | | 832867837 | pack(11822-0685) |

| Establishment | | | |
|-------------------------|---------|-----------|----------------------------|
| Name | Address | ID/FEI | Business Operations |
| LNK International, Inc. | | 832867894 | manufacture(11822-0685) |

Revised: 6/2023 Rite Aid Corporation