

SLEEP AID MAXIMUM STRENGTH- diphenhydramine hcl capsule Fred's Inc

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.

Drug Facts

Active ingredient (in each softgel)

Diphenhydramine HCl 50 mg

Purpose

Nighttime sleep-aid

Use

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
- 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.

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 (1-800-222-1222).

Directions

- adults and children 12 years of age and over: 1 softgel (50 mg) at bedtime if needed, or as directed by a doctor

Other information

- store between 15-30°C (59-86°F)

Inactive ingredients

edible white ink, FD&C blue #1, gelatin, glycerin, polyethylene glycol, propylene glycol*, purified water, sorbitol sorbitan*

*contains one or more of these ingredient

Questions or comments?

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

Principal Display Panel

Compare to the Active Ingredient in Unisom® SleepGels®†

Maximum Strength

Sleep-Aid

Diphenhydramine HCl, 50 mg

Nighttime Sleep-Aid • Safe, Non Habit-Forming

- Fall Asleep Fast
- Sleep Soundly
- Wake Up Refreshed

SOFTGELS (LIQUID FILLED)

†This product is not manufactured or distributed by Chattem, Inc., distributor of Unisom® SleepGels®.

DISTRIBUTED BY: fred's, Inc.

4300 NEW GETWELL RD, MEMPHIS, TN 38118

www.fredsinc.com

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

**TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS
BROKEN OR MISSING.**

Package Label



NDC 55315-735-32

Compare to the Active Ingredient in Unisom® SleepGels®†

Maximum Strength Sleep Aid

Diphenhydramine HCl, 50 mg

Nighttime Sleep-Aid • Safe, Non Habit-Forming

**32 SOFTGELS (LIQUID FILLED)
50 MG EACH**

ACTUAL SIZE



- Fall Asleep Fast
- Sleep Soundly
- Wake Up Refreshed

Lot No.:
Exp. Date:

†This product is not manufactured or distributed by Chatterm, Inc., distributor of Unisom® SleepGels®.

DISTRIBUTED BY: fred's, Inc.
4300 NEW GETWELL RD, MEMPHIS, TN 38118
www.fredsinc.com

100% satisfaction guaranteed

Questions or comments:
1-855-331-FRED (3733)

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.



PLD-E270
FC005410

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|--|
| Drug Facts |
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| Purpose |
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| 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. |
| 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 (1-800-222-1222). |
| Directions |
| ■ adults and children 12 years of age and over: 1 softgel (50 mg) at bedtime if needed, or as directed by a doctor |
| Other information ■ store between 15-30°C (59-86°F) |
| Inactive ingredients edible white ink, FD&C blue #1, gelatin, glycerin, polyethylene glycol, propylene glycol, purified water, sorbitan, sorbitol |
| "contains one or more of these ingredients" |
| Questions or comments? Call 1-877-753-3935 Monday-Friday 9AM-5PM EST |

FRED'S PHARMACY Maximum Strength Sleep Aid

SLEEP AID MAXIMUM STRENGTH

diphenhydramine hcl capsule

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:55315-735 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|----------------------------------|----------|
| DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M) | DIPHENHYDRAMINE HYDROCHLORIDE | 50 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |
| GELATIN (UNII: 2G86QN327L) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| WATER (UNII: 059QF0KO0R) | |
| SORBITAN (UNII: 6O92ICV9RU) | |
| SORBITOL (UNII: 506T60A25R) | |

Product Characteristics

| | | | |
|-----------------|---------|---------------------|-------------------|
| Color | blue | Score | no score |
| Shape | CAPSULE | Size | 13mm |
| Flavor | | Imprint Code | P50;A99;D50;AP018 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:55315-735-32 | 1 in 1 BOX | 12/31/2018 | 12/27/2024 |
| 1 | | 32 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part341 | 12/31/2018 | 12/27/2024 |

