

SLEEP-AID NIGHTTIME- diphenhydramine hydrochloride capsule, liquid filled P & L Development, LLC

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 25 mg

Purpose

Nighttime sleep-aid

Uses

- for the 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
- glaucoma
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers or any other sleep-aid.

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.

Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions

- take only one dose (2 softgels) per day (24 hours)
- swallow whole; do not crush, chew, or dissolve
- adults & children 12 years and over: take 2 softgels at bedtime, if needed, or as directed by a doctor
- children under 12 years of age: do not use

Other information

- store between 20-25° C (68-77° F)
- avoid excessive heat above 40° C (104° F) and high humidity
- protect from light

Inactive ingredients

edible white ink, FD&C blue #1, FD&C red #40, gelatin, glycerin, polyethylene glycol 400, propylene glycol*, purified water, sorbitol, sorbitan

*may contain this ingredient

Questions or comments?

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

Principal Display Panel

nighttime sleep-aid

Diphenhydramine HCl 25 mg

nighttime sleep-aid

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

See Warnings

softgels**

(**liquid-filled capsules)

†Compare to the active ingredient in ZZZQUIL®

This product is not manufactured or distributed by The Procter & Gamble Company. ZZZQUIL® is a registered trademark of The Procter & Gamble Company.

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Distributed by: **PL Developments,**

200 Hicks Street,

Westbury, NY 11590

Package Label

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|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>Questions or comments? Call 1-877-753-3935 Monday-Friday 9AM-5PM EST</p> | <p>Drug Facts Active ingredient (in each softgel) Diphenhydramine HCl 25 mg.....Nighttime sleep-aid</p> |
| <p>Inactive ingredients edible white ink, FD&C blue #1, FD&C red #40, gelatin, glycerin, polyethylene glycol 400, propylene glycol, purified water, sorbitan, sorbitol *may contain this ingredient</p> | <p>Uses <ul style="list-style-type: none"> for the relief of occasional sleeplessness reduces time to fall asleep if you have difficulty falling asleep </p> |
| <p>Other information <ul style="list-style-type: none"> store between 20-25°C (68-77°F) avoid excessive heat above 40°C (104°F) and high humidity protect from light </p> | <p>Warnings <ul style="list-style-type: none"> Do not use <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> a breathing problem such as emphysema or chronic bronchitis glaucoma trouble urinating due to an enlarged prostate gland </p> |
| <p>Directions <ul style="list-style-type: none"> take only one dose (2 softgels) per day (24 hours) swallow whole; do not crush, chew, or dissolve adults and children 12 years and over: take 2 softgels at bedtime, if needed, or as directed by a doctor children under 12 years of age: do not use </p> | <p>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.</p> |
| <p>Drug Facts (continued) <ul style="list-style-type: none"> 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) </p> | <p>Purpose Nighttime sleep-aid</p> |

Failure to follow these warnings could result in serious consequences.



nighttime sleep-aid



nighttime sleep-aid

diphenhydramine HCl 25 mg
nighttime sleep-aid

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

see warnings

48 softgels**
(**liquid-filled capsules)

Lot No.:
Exp. Date:

Compare to the active ingredient in ZZZQUIL™

Distributed by: **PL Developments**
200 Hicks Street, Westbury, NY 11590

PLD-A188E
FC004610



WELLNESS BASICS Nighttime Sleep-Aid

SLEEP-AID NIGHTTIME

diphenhydramine hydrochloride capsule, liquid filled

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:59726-405 |
| 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 |
|---------------------------------------------------|----------|
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |
| GELATIN (UNII: 2G86QN327L) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) | |
| WATER (UNII: 059QF0KO0R) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| SORBITOL (UNII: 506T60A25R) | |
| SORBITAN (UNII: 6O92ICV9RU) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |

Product Characteristics

| | | | |
|-----------------|---------|---------------------|----------|
| Color | purple | Score | no score |
| Shape | CAPSULE | Size | 15mm |
| Flavor | | Imprint Code | A41;602 |
| Contains | | | |

Packaging

| | | | |
|--|--|------------------------|----------------------|
| | | Marketing Start | Marketing End |
|--|--|------------------------|----------------------|

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--------------------------------------------------------|----------------------|--------------------|
| 1 | NDC:59726-405-48 | 48 in 1 CARTON | 12/31/2017 | 04/26/2024 |
| 1 | | 1 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 | 12/31/2017 | 04/26/2024 |

Labeler - P & L Development, LLC (800014821)

Revised: 10/2021

P & L Development, LLC