

LEADER NIGHTTIME SLEEP-AID- diphenhydramine hydrochloride liquid CARDINAL HEALTH

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.

Sleep Aid Diphenhydramine HCl 50 mg Nighttime Sleep Aid Berry Flavor 6 FL OZ 177mL

Drug Facts

Active ingredient (in each 30 mL)

Diphenhydramine HCl 50 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
- with other drugs that cause drowsiness such as antihistamines and nighttime cold/flu products

Ask a doctor before use if you have

- a breathing problem such as asthma, emphysema, or chronic bronchitis
- glaucoma
- difficulty in urination due to enlargement of the prostate gland
- heart disease

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 and other drugs that cause drowsiness
- drowsiness will occur

- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if sleeplessness persists continuously for more than two 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:

Taking more than directed can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away. 1-800-222-1222

Directions

- take only one dose per day (24 hours) – see Overdose warning
- Measure with dosing cup provided.

| | |
|------------------------------------|---|
| adults & children 12 yrs & over | One Dose = 30 mL at bed time if needed or as directed by a doctor |
| Children under 12 yrs | Do not use |

Other information

- each 30 mL dose contains: **sodium 23 mg**
- store at room temperature
- protect from light. Does not meet USP <671>

Inactive ingredients

anhydrous citric acid, FD&C blue 1, FD&C red 40, flavor, glycerin, potassium citrate, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum.

Questions or comments?

1-866-467-2748

PRINCIPAL DISPLAY PANEL

LEADER

NDC **70000-0174-2**

Sleep Aid

Diphenhydramine HCl , 50 mg

Nighttime Sleep-Aid

COMPARE TO ZZZQUIL™ NIGHTTIME SLEEP-AID active ingredient*

100% Money Back Guarantee

Berry Flavor

Naturally & Artificially Flavored

Non-Habit forming

Alcohol- Free

Not for Treating Cold or Flu

See Warnings

6 FL OZ (177 mL)

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Failure to follow these warnings could result in serious consequences.

TAMPER EVIDENT: Do not use if printed shrink band is missing or broken

DISTRIBUTED BY: CARDINAL HEALTH

DUBLIN, OHIO 43017

www.myleader.com 1-800-200-6313

*This product is not manufactured or distributed by Procter & Gamble, the owner of the registered trademark ZzzQuil™ Nighttime Sleep-Aid.

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Drug Facts

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(in each 30mL dose cup)

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LEADER²

Sleep Aid

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Nighttime Sleep-Aid

Berry Flavor

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COMPARE TO

ZzzQUILTM

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SLEEP-AID

active ingredient*

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Drug Facts (continued)

■ a breathing problem such as asthma, emphysema, chronic bronchitis

■ glaucoma

■ difficulty in urination due to enlargement of prostate gland

■ heart disease

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers or any other sleep medicine.

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CIN 5320775 REV. 3/17

0 96295 13166 6 EXP:

LOT:

Drug Facts (continued)

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Directions ■ take only one dose per day (24 hours) - see Overdose warning ■ use dose cup

adults & children 12 yrs & over One Dose = 30 mL at bed time if needed or as directed by a doctor

Other information ■ each 30 mL dose contains: sodium 23 mg ■ store at room temperature ■ protect from light. Does not meet USP <671>.

Inactive ingredients anhydrous citric acid, FD&C blue 1, FD&C red 40, flavor, glycerin, potassium citrate, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum.

Questions or comments? 1-866-467-2748

STOP PEELING HERE

LEADER NIGHTTIME SLEEP-AID

diphenhydramine hydrochloride liquid

| Product Information | | | |
|--|----------------|-------------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:70000-0174 |
| 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 in 30 mL |
| Inactive Ingredients | | | |
| Ingredient Name | | | Strength |
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) | | | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | | | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | | | |

| | |
|---|--|
| GLYCERIN (UNII: PDC6A3C0OX) | |
| POTASSIUM CITRATE (UNII: EE90ONI6FF) | |
| WATER (UNII: 059QF0KO0R) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| SORBITOL (UNII: 506T60A25R) | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |

Product Characteristics

| | | | |
|-----------------|--------|---------------------|--|
| Color | PURPLE | Score | |
| Shape | | Size | |
| Flavor | BERRY | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:70000-0174-2 | 177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/13/2017 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part338 | 03/13/2017 | |

Labeler - CARDINAL HEALTH (063997360)

Revised: 10/2023

CARDINAL HEALTH