

SLEEP TIME- diphenhydramine hcl liquid

HyVee 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.

Hy-Vee, Inc. Sleep Time Drug Facts

Active ingredient (in each 30 mL dose cup)

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
- with other Nighttime products

Ask a doctor before use if you have

- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- difficulty in urination due to an 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 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
- 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 cup contains: sodium 20 mg
- store at 20-25°C (68-77°F)
- protect from light. Does not meet USP <671>.

Inactive Ingredients

alcohol, anhydrous citric acid, FD&C blue #1, FD&C red #40, flavor, high fructose corn syrup, poloxamer 407, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium citrate

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

Compare to Vicks® ZzzQuil® Nighttime Sleep-Aid active ingredient

Sleep Time

Night Time Sleep-Aid

Berry Flavor

Diphenhydramine HCl

50 mg per 30 mL

Non-Habit Forming

Nor for treating Cold or Flu

See Warnings

10% ALCOHOL

12 FL OZ (355 mL)

Drug Facts (continued)

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Questions or comments? 1-800-719-9260

DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING

*This product is not manufactured or distributed by Procter & Gamble, distributor of Vicks® ZzzQuil® Nighttime Sleep-Aid.

DISTRIBUTED BY HY-VEE, INC.
WEST DES MOINES, IA 50266
SATISFACTION GUARANTEED
CALL 1-800-289-8343
www.hy-vee.com



NDC 42507-186-40

Compare to Vicks® ZzzQuil®
Nighttime Sleep-Aid active ingredient*



SleepTime

Night Time Sleep-Aid



Diphenhydramine HCl
50 mg per 30 mL

Non-Habit Forming
Not for treating Cold or Flu
See Warnings

10% ALCOHOL

12 FL OZ
(355 mL)

Failure to follow these warnings could result in serious consequences.

Drug Facts

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|---|---------------------|
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SLEEP TIME

diphenhydramine hcl liquid

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:42507-186 |
| 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 |
|---|----------|
| ALCOHOL (UNII: 3K9958V90M) | |
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) | |
| FD&C BLUE NO. 1 (UNII: HBR47K3TBD) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S) | |
| POLOXAMER 407 (UNII: TUF2IVW3M2) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| WATER (UNII: 059QF0KO0R) | |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| SODIUM CITRATE (UNII: 1Q73Q2JULR) | |

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:42507-186-30 | 177 mL in 1 BOTTLE | | |
| 2 | NDC:42507-186-40 | 355 mL in 1 BOTTLE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part338 | 07/08/2013 | |

Labeler - HyVee Inc (006925671)

Revised: 9/2013

HyVee Inc