

DG HEALTH SLEEP AID- diphenhydramine hcl solution
Dolgenercorp, 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.

Dolgenercorp, LLC Sleep Aid 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

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.

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)
- only use the dose cup provided

| | |
|---------------------------------|--|
| adults & children 12 yrs & over | 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 contains:** sodium 20 mg
- store at 20-25°C (68-77°F)

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?

1-888-309-9030

Package/Label Principal Display Panel

Compare to the active ingredient of ZzzQuil®

Night Time

Sleep Aid

Diphenhydramine HCl 50mg per 30mL

Non-Habit Forming

Not For Treating Cold or Flu

ALCOHOL 10%

6 FL OZ (177 mL)

50 mg

Mixed Berry Flavor

| | | | | | | |
|---|--|---------------------------------|--|-----------------------|------------|---|
| <p>Drug Facts (continued)</p> <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> ■ a breathing problem such as emphysema or chronic bronchitis ■ glaucoma ■ difficulty in urination due to enlargement of the prostate gland <p>Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers</p> <p>When using this product</p> <ul style="list-style-type: none"> ■ avoid alcoholic beverages <p>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.</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> | <p>Drug Facts (continued)</p> <p>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>Directions</p> <ul style="list-style-type: none"> ■ take only one dose per day (24 hours) ■ only use the dose cup provided <table border="1"> <tr> <td>adults & children 12 yrs & over</td> <td>30 mL at bed time if needed or as directed by a doctor</td> </tr> <tr> <td>children under 12 yrs</td> <td>do not use</td> </tr> </table> <p>Other Information</p> <ul style="list-style-type: none"> ■ each 30 mL contains: sodium 20 mg ■ store at 20-25°C (68-77°F) | adults & children 12 yrs & over | 30 mL at bed time if needed or as directed by a doctor | children under 12 yrs | do not use | <p>Drug Facts (continued)</p> <p>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</p> <p>Questions or comments? 1-888-309-9030</p> |
| adults & children 12 yrs & over | 30 mL at bed time if needed or as directed by a doctor | | | | | |
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DG HEALTH SLEEP AID

diphenhydramine hcl solution

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:55910-186 |
| 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: H3R47K3TBD) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S) | |
| POLOXAMER 407 (UNII: TUF2IVW3M2) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| WATER (UNII: 059QF0K00R) | |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| SODIUM CITRATE, UNSPECIFIED FORM (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:55910-186-30 | 177 mL in 1 BOTTLE; Type 0: Not a Combination Product | 05/11/2015 | |
| 2 | NDC:55910-186-34 | 237 mL in 1 BOTTLE; Type 0: Not a Combination Product | 04/05/2018 | 01/31/2020 |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part338 | 05/11/2015 | |

Labeler - Dolgencorp, LLC (068331990)

Revised: 5/2021

Dolgencorp, LLC