NIGHTTIME SLEEP AID- diphenhydramine hcl liquid Care One (American Sales Company)

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

- with any other product containing diphenhydramine, even one used on the skin
- for children under 12 years of age
- with other drugs that cause drowsiness such as antihistamines, nighttime cold/flu products, and other nighttime sleep-aids

Ask a doctor before use if you have

- heart disease
- glaucoma
- breathing problem such as asthma, emphysema, or chronic bronchitis
- 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

- drowsiness will occur
- avoid alcoholic drinks and other drugs that cause drowsiness
- be careful when driving a motor vehicle or operating machinery

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.

Directions

- take only one dose per day (24 hours) (see overdose warning)
- mL=milliliter
- measure only with dosing cup provided.Do not use any other dosing device
- keep dosing cup with product
- adults and children 12 years and over
 one dose=30 mL at bedtime if needed, or as directed by a doctor
- children under 12 years do not use

Other information

- each 30 mL contains: sodium 23 mg
- store at 20-25°C (68-77°F)
- do not refrigerate
- protect from light

Inactive ingredients

citric acid, ethyl alcohol, FD&C blue #1, FD&C red #40, flavor, high fructose corn syrup, polyoxyl 40 stearate, propylene glycol, purified water, saccharin sodium , sodium benzoate, trisodium citrate dihydrate

Questions or comments?

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

Principal Display Panel

Compare to the Active Ingredient in ZZZQUIL®*

NIGHTTIME SLEEP AID

Diphenhydramine HCI 50 mg

Alcohol 10%

Non-Habit-Forming

Not for treating cold or flu

Berry Flavor

FL OZ (mL)

Failure to follow these warnings could result in serious consequences

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

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

DISTRIBUTED BY

FOODHOLD USA LLC

LANDOVER, MD 20785

1-877-846-9949

Package Label



| NIGHTTIME SLEEP AID diphenhydramine hcl liquid | | | | | |
|---|----------------|--------------------|---------------|--|--|
| Product Information | | | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:41520-034 | | |
| Route of Administration | ORAL | | | | |
| | | | | | |
| Active Ingredient/Active Moiety | | | | | |

| Ingred | ient Name | | Basis of Strengt | th Str | ength |
|--|-----------------------------|--------------|----------------------------------|--------------|------------|
| DIPHENHYDRAMINE HYDROCHLO (DIPHENHYDRAMINE - UNII:8GTS82S8 | | 40) | DIPHENHYDRAMINE HYDROCHLORIDE | 50 m in 3 | ng 0 mL |
| | | | | | |
| Inactive Ingredients | | | | | |
| | Ingredient Nam | е | | Strength | |
| ANHYDROUS CITRIC ACID (UNII: X | F417D3PSL) | | | | |
| PROPYLENE GLYCOL (UNII: 6DC9Q | 167V3) | | | | |
| POLYOXYL 40 STEARATE (UNII: 13 | A4J4NH9I) | | | | |
| WATER (UNII: 059QF0KO0R) | | | | | |
| SODIUM BENZOATE (UNII: OJ245FE | 5EU) | | | | |
| SACCHARIN SODIUM ANHYDROUS | 5 (UNII: I4807BK602) | | | | |
| TRISODIUM CITRATE DIHYDRATE | (UNII: B22547B95K) | | | | |
| HIGH FRUCTOSE CORN SYRUP (U | NII: XY6UN3QB6S) | | | | |
| FD&C BLUE NO. 1 (UNII: H3R47K31 | BD) | | | | |
| ALCOHOL (UNII: 3K9958V90M) | | | | | |
| FD&C RED NO. 40 (UNII: WZB9127 | XOA) | | | | |
| | | | | | |
| Product Characteristics | | | | | |
| Color | | Score | | | |
| Shape | | Size | | | |
| Flavor | BERRY | Imprint Code | | | |
| Contains | | | | | |
| | | | | | |
| | | | | | |

| # | ltem Code | Package Description | Marketing Start Date | Marketing End Date |
|---|----------------------|--|-------------------------|-----------------------|
| 1 | NDC:41520- 034-06 | 177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 06/30/2015 | |
| 2 | NDC:41520- 034-12 | 355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 06/30/2015 | |

Marketing Information

| Marketing | Application Number or Monograph | Marketing Start | Marketing End |
|--------------------|---------------------------------|-----------------|---------------|
| Category | Citation | Date | Date |
| OTC Monograph Drug | M012 | 06/30/2015 | |

Labeler - Care One (American Sales Company) (809183973)

Revised: 3/2024