

EZ NITE SLEEP AID- diphenhydramine hcl liquid
EQUATE (Wal-Mart Stores, 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.

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 and nighttime cold/flu products, and other nighttime sleep-aids

Ask a doctor before use if you have

- heart disease
- glaucoma
- a 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
- shake well before using
- 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=30mL 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, FD&C blue #1, FD&C red #40, flavor, high fructose corn syrup, polyoxyl 40 stearate, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium citrate

Questions or comments?

Call **1-888-287-1915**

Principal Display Panel

Compare to ZZZQUIL® Active Ingredient*

EZ Nite Sleep Aid

Diphenhydramine HCl 50 mg

Nighttime Sleep-Aid

- non habit forming
- berry flavor

Alcohol free

Not for treating Cold or Flu

See Warnings

FL OZ (mL)

Failure to follow these warnings could result in serious consequences

Distributed by: Wal-Mart Stores, Inc.,

Bentonville, AR 72716

*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 PRINTED SAFETY SEAL AROUND DOSAGE CUP OR UNDER CAP IS BROKEN OR MISSING.

Package Label

Drug Facts (continued)

Directions

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NDC 49035-675-12



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to ZZZQUIL®
Active
Ingredient*

EZ Nite Sleep Aid

**Diphenhydramine
HCl 50 mg**

Nighttime Sleep-Aid

- Non-Habit
Forming
- Berry Flavor

Alcohol-Free

Not for treating Cold or Flu
See Warnings

12 FL OZ (355mL)

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|--------------------------------------|---------------------|
| Diphenhydramine HCl 50 mg..... | Nighttime sleep-aid |

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Equate EZ Nite Sleep Aid

EZ NITE SLEEP AID

diphenhydramine hcl liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:49035-675 |
| 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) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| POLYOXYL 40 STEARATE (UNII: 13A4J4NH9J) | |

| | |
|---|--|
| WATER (UNII: 059QF0KO0R) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| SACCHARIN SODIUM ANHYDROUS (UNII: I4807BK602) | |
| TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K) | |
| HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S) | |
| FD&C BLUE NO. 1 (UNII: HBR47K3TBD) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |

Product Characteristics

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

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:49035-675-12 | 355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 10/31/2015 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC MONOGRAPH FINAL | part338 | 10/31/2015 | |

Labeler - EQUATE (Wal-Mart Stores, Inc.) (051957769)