

ZZZQUIL NIGHTTIME SLEEP-AID- diphenhydramine hydrochloride capsule, gelatin coated
The Procter & Gamble Manufacturing Company

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.

ZzzQuil™

NIGHTTIME SLEEP-AID

Drug Facts

Active ingredients (in each liquicap)

Diphenhydramine HCl 25 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 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.

Directions

- take only one dose per day (24 hours) - see Overdose warning

adults & children 12 yrs & over

One dose = TWO 25 mg LiquiCaps (50 mg) at bed time if needed or as directed by a doctor

children under 12 yrs

do not use

Other information

- store at 20-25° C (68-77° F)
- avoid excessive heat above 40° C (104° F)
- protect from light.

Inactive ingredients

FD&C Blue No. 1, FD&C Red No. 40, gelatin, glycerin, pharmaceutical ink*, polyethylene glycol, purified water, sorbitol sorbitan solution.

*May contain this ingredient.

Questions?

1-877-881-5813

Dist. by Procter & Gamble, Cincinnati OH 45202.

PRINCIPAL DISPLAY PANEL - 12 Capsule Carton

NEW *From the makers of* VICKS[®] NyQuil[®]

ZzzQuil[™]

NIGHTTIME SLEEP-AID

Diphenhydramine HCl

Non-Habit Forming

See Warnings

Not for treating Cold or Flu

12 LiquiCaps



ZZZQUIL NIGHTTIME SLEEP-AID
diphenhydramine hydrochloride capsule, gelatin coated

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:37000-501 |
| 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 2 |

Inactive Ingredients

| Ingredient Name | Strength |
|---|-----------------|
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |
| GELATIN (UNII: 2G86QN327L) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| WATER (UNII: 059QF0KO0R) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| SORBITOL (UNII: 506T60A25R) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |

Product Characteristics

| | | | |
|-----------------|---------|---------------------|----------|
| Color | purple | Score | no score |
| Shape | CAPSULE | Size | 15mm |
| Flavor | | Imprint Code | Zzz |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:37000-501-12 | 6 in 1 CARTON | 12/08/2011 | |
| 1 | | 2 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 2 | NDC:37000-501-24 | 12 in 1 CARTON | 12/08/2011 | |
| 2 | | 2 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 3 | NDC:37000-501-48 | 24 in 1 CARTON | 12/08/2011 | |
| 3 | | 2 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 4 | NDC:37000-501-72 | 36 in 1 CARTON | 12/08/2011 | |
| 4 | | 2 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 5 | NDC:37000-501-96 | 2 in 1 CELLO PACK | 01/01/2020 | |
| 5 | | 24 in 1 CARTON | | |
| 5 | | 2 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| OTC monograph final | part338 | 12/08/2011 | |

Labeler - The Procter & Gamble Manufacturing Company (004238200)

Revised: 2/2020

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