**QUALITY CHOICE NIGHTTIME SLEEP-AID- diphenhydramine hydrochloride capsule, liquid filled**
**Chain Drug Marketing Association, 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.*

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**QUALITY CHOICE Nighttime Sleep-Aid**

## *Drug Facts*

### *Active ingredient (in each softgel)*

Diphenhydramine HCl 25 mg

### *Purpose*

Nighttime sleep-aid

### *Uses*

•for 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

**Ask a doctor before use if you have** •glaucoma •heart diseases •a breathing problem such as emphysema, asthma, or chronic bronchitis •difficulty in urination due to enlargement of the prostate gland

**Ask a doctor or pharmacist before use if you are** taking sedatives, tranquilizers, or any other sleep aid

**When using this product** •avoid alcoholic beverages 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 a serious underlying medical illness.

**If pregnant or breast-feeding,** ask a health professional before use.

**Keep out of reach of children. Overdose warning:** In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as children even if you do not notice any signs or symptoms.

### *Directions*

•take only one dose per day (24 hours)

| | |
|---|---|
| adults and children 12 years and over | take 2 softgels at bedtime if needed or as directed by a doctor |
| children under 12 years | 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*

edible white ink, FD&C blue#1, FD&C red#40, gelatin, glycerin, isopropyl alcohol, medium chain triglycerides, polyethylene glycol, povidone, purified water, sorbitol sorbitan solution

### *Questions or comments?*

**1-888-577-8033** Monday-Friday 8am-4pm EST

***Compare to active ingredient in VICKS® ZzzQUIL™ Liquicaps™**

Non-habit Forming
Fall Asleep Fast

**READ AND KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION**



**TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING**

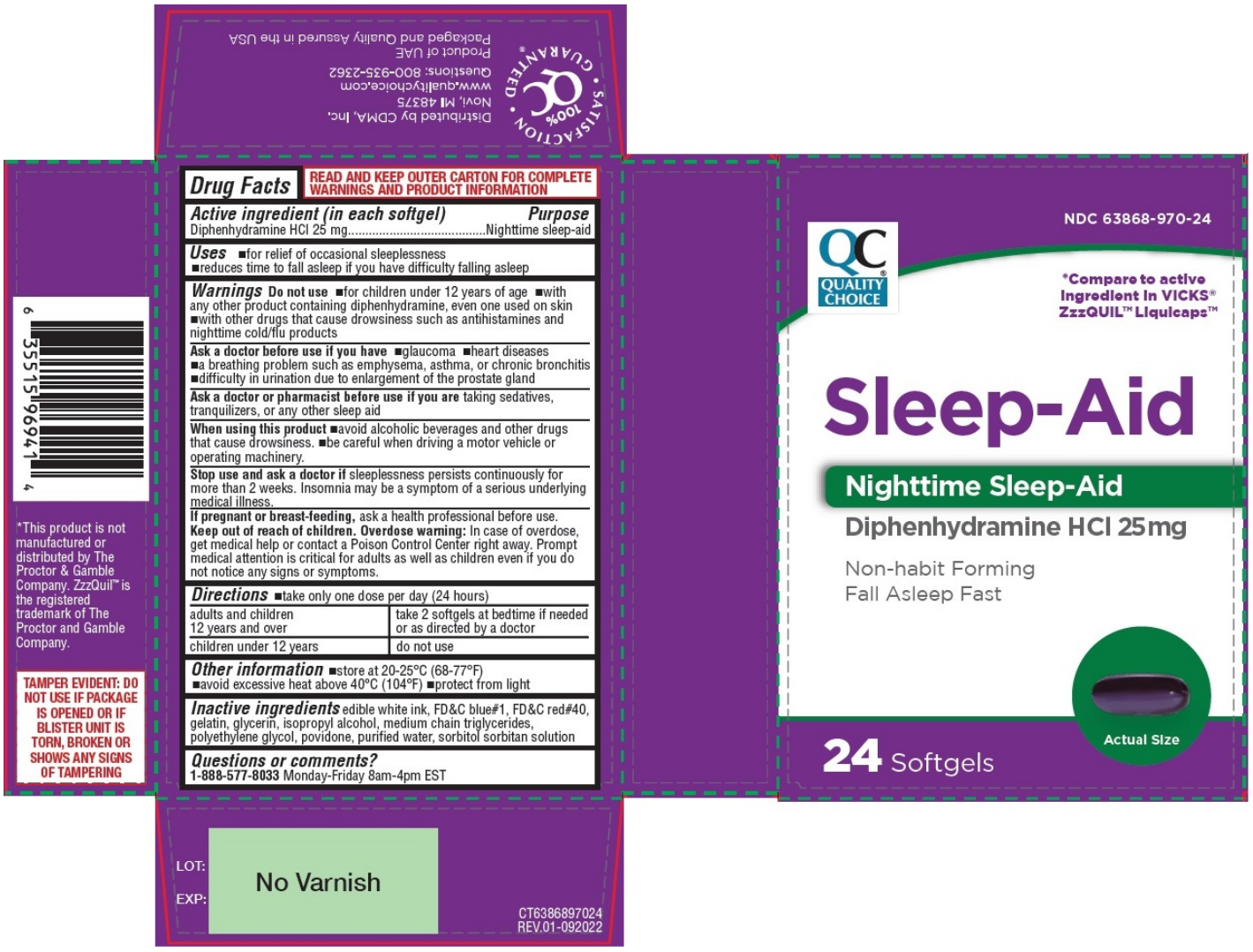
**QC 100% SATISFACTION GUARANTEED**

Distributed by CDMA, Inc.
Novi, MI 48375
www.qualitychoice.com
Questions: 800-935-2362

Product of UAE
Packaged and Quality Assured in the USA

REV.01-092022

## Packaging




# QUALITY CHOICE NIGHTTIME SLEEP-AID

diphenhydramine hydrochloride capsule, liquid filled

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:63868-970 |
| **Route of Administration** | ORAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **DIPHENHYDRAMINE HYDROCHLORIDE** (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M) | DIPHENHYDRAMINE HYDROCHLORIDE | 25 mg |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |
| **FD&C RED NO. 40** (UNII: WZB9127XOA) | |
| **GELATIN, UNSPECIFIED** (UNII: 2G86QN327L) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **ISOPROPYL ALCOHOL** (UNII: ND2M416302) | |
| **MEDIUM-CHAIN TRIGLYCERIDES** (UNII: C9H2L21V7U) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |
| **POVIDONE, UNSPECIFIED** (UNII: FZ989GH94E) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **SORBITOL** (UNII: 506T60A25R) | |
| **SORBITAN** (UNII: 6O92ICV9RU) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | purple | **Score** | no score |
| **Shape** | OVAL | **Size** | 15mm |
| **Flavor** | | **Imprint Code** | 779 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:63868-970-24 | 2 in 1 CARTON | 03/28/2023 | |
| **1** | | 12 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 | 03/28/2023 | |

## Labeler - Chain Drug Marketing Association, Inc. (011920774)

Revised: 7/2023 Chain Drug Marketing Association, Inc.