## TOPCARE ZZZ SLEEP- diphenhydramine hcl capsule, liquid filled Topco Associates 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.

-----

## Topco Associates LLC. ZZZ® Sleep Drug Facts

#### Active ingredient (in each softgel)

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 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)

adults & children 12 yrs & over	2 softgels at bedtime 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**

edible ink, FD&C blue #1, FD&C red #40, gelatin, glycerin, polyethylene glycol, purified water, sorbitol sorbitan solution

#### Questions or comments?

1-888-423-0139

## Package/Label Principal Display Panel

TopCare® health

COMPARE TO VICKS® ZZZQUIL® ACTIVE INGREDIENT

**NIGHTTIME** 

ZZZ Sleep®

DIPHENHYDRAMINE HCl 25 mg

**NIGHTTIME SLEEP-AID** 

- Non-Habit Forming
- Not for Treating Cold or Flu

See Warnings 12 SOFTGELS actual size

FD&C red # 40, gelatin, glycerin, polyethylene glycol, purified water, sorbitol sorbitan solution In active in gredients edible in k, rD&C b to e#1, **Drug Facts** (continued)

■ protect from light

■ avoid excessive heat above 40°C (104°F)

■ store at 20-25°C (68-77°F)

noitem information

(beuritnoo) **etact** (continued)





DO NOT USE IF BLISTER UNIT IS BROKEN OR TORN

This TopCare<sup>(2)</sup> product is laboratory tested to guarantee its highest quality Your total satisfaction is guaranteed.

\*This product is not manufactured or distributed by Procter & Gamble, distributor of

<b>A</b>	eeu fon o b	children un der 12 yrs
	2 softgels at bedtime if needed or as directed by a doctor	adults & child ren 12 yrs & over
		/ / / / / /

■ take only one dose per day (24 hours)

#### D irections

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away If pregnant or breast-feeding, ask a health profession a before use.

symptomof serious underlying medical illness.

Stopuse and ask a doctor if sleeplessness persists continuously for more than 2 weeks. Insom niamay be a When using this product avoid alcoholic beverages

Ask a doc tor or pharma cist before use if you are taking sed atives or tranquifzers

- difficulty in unination due to en largement of the prostate gland
  - a breathing problem such as emphysema or chronic bronchitis Ask a doctor be fore use if you have
- with any other product containing dip henhyd ramine, even one used on skin Do not use ■ for children und er 12 years of ag e sbuju.ie M
- for the relief of occasional sleeplessness
  reduces time to fall as leep if you have difficulty falling as leep

bis-qəəlz əmittigiM.

Purpose

.....gm ZS IOH ənimsəbydnədqi 🛚

(ləptios dəsə ni) traibərpni əvitəA

Drug Facts



DISTRIBUTED BY TOPCO ASSOCIATES LLC ELK GROVE VILLAGE, IL 60007 ©TOPCO PERA0521 QUESTIONS? 1-888-423-0139 topcare@topco.com www.topcarebrand.com



Scan here for more information or call 1-888-423-0139

NDC36800-507-53



COMPARE TO VICKS® ZZZQUIL® ACTIVE INGREDIENT\*

NIGHTTIME

# ZZZ Sleep®

DIPHENHYDRAMINE HCI 25 mg

## **NIGHTTIME SLEEP-AID**

- Non-Habit Forming
- Not for Treating Cold or Flu See Warnings

12 SOFTGELS





05253 88 C6

#### **TOPCARE ZZZ SLEEP**

diphenhydramine hcl capsule, liquid filled

#### **Product Information**

**Product Type** HUMAN OTC DRUG **Item Code (Source)** NDC:36800-507

**Route of Administration** ORAL

## **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6IAD40)	DIPHENHYDRAMINE	

(DIPHENHYDRAMINE - UNII:8GTS82S83M)

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)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
WATER (UNII: 059QF0KO0R)		
CORRIGON (UNIV. FOCTCOADER)		

SORBITOL (UNII: 506T60A25R) SORBITAN (UNII: 6092ICV9RU)

#### **Product Characteristics**

Packaging

1

Color	PURPLE	Score	no score
Shape	OVAL	Size	15mm
Flavor		Imprint Code	052
Contains			

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-507- 53	6 in 1 CARTON	01/28/2014	

Product 2 NDC:36800-507- 24 in 1 CARTON 01/28/2014 67

2 in 1 BLISTER PACK; Type 0: Not a Combination

2 in 1 BLISTER PACK; Type 0: Not a Combination Product

**3** NDC:36800-507- 12 in 1 CARTON

01/28/2014

	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 fina	part338	01/28/2014		

## Labeler - Topco Associates LLC (006935977)

Revised: 1/2023 Topco Associates LLC