TOPCARE ZZZ SLEEP- diphenhydramine hcl solution Topco Associates LLC

Topco Associates LLC. ZZZ Sleep® Drug Facts

Active ingredient (in each 30 mL)

Diphenhydramine HCI 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

- 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 (1-800-222-1222).

Directions

- take only one dose per day (24 hours)
- only use the dose cup provided

adults & children 12 yrs & over	30 mL at bed time if needed or as directed by a doctor
children under 12 yrs	do not use

Other information

- each 30 mL contains: sodium 20 mg
- store at 20-25°C (68-77°F)

Inactive ingredients

alcohol, anhydrous citric acid, FD&C blue #1, FD&C red #40, flavor, high fructose corn syrup, poloxamer 407, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium citrate

Questions or comments?

1-888-423-0139

Package/Label Principal Display Panel

TopCare® health

NIGHTTIME

COMPARE TO VICKS® ZZZQUIL® ACTIVE INGREDIENT

ZZZ Sleep®

DIPHENHYDRAMINE HCI 50 mg per 30 mL

NIGHTTIME SLEEP-AID

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

ALCOHOL 10%

6 FL OZ (177 mL)

BERRY FLAVOR



CODE

AREA

: 18630 88 F6

DISTRIBUTED BY QUESTIONS? 1-888-423-0139 topcare@topco.com www.topcarebrand.com



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





distributed by Procter & Gamble, distributor of Vicks® ZzzQuil®.

VDC 36800-200-30 TopCare.

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BERRY FLAVOR

COMPARE TO VICKS® ZZZQUIL®

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PEEL BACK FOR DRUG FACTS



Drug Facts (continued)

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Drug Facts (continued)

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Directions

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- only use the dose cup provided

adults & children 30 mL at bed time 12 yrs & over if needed or as directed by a doctor children under do not use

12 yrs

Other information

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Drug Facts (continued)

Inactive ingredients alcohol, anhydrous citric acid, FD&C blue #1, FD&C red #40, flavor, high fructose com syrup, poloxamer 407, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium citrate

Questions or comments? 1-888-423-0139

TOPCARE ZZZ SLEEP

diphenhydramine hcl solution

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:36800-200

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6|AD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)

DIPHENHYDRAMINE **HYDROCHLORIDE**

50 ma in 30 mL

Inactive Ingredients

Ingredient Name Strength

ALCOHOL (UNII: 3K9958V90M)

ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)

FD&C BLUE NO. 1 (UNII: H3R47K3TBD) FD&C RED NO. 40 (UNII: WZB9127XOA)

HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)

POLOXAMER 407 (UNII: TUF2IVW3M2)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	

Product Characteristics				
Color	PURPLE	Score		
Shape		Size		
Flavor	BERRY	Imprint Code		
Contains				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-200- 30	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/23/2013	06/30/2024
2	NDC:36800-200- 40	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/20/2013	
3	NDC:36800-200- 34	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/19/2013	09/30/2020
4	NDC:36800-200- 50	2 in 1 PACKAGE	08/20/2013	
4		355 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M010	08/20/2013		

Labeler - Topco Associates LLC (006935977)

Revised: 10/2024 Topco Associates LLC