

TOPCARE ZZZ SLEEP- diphenhydramine hcl solution
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 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

- 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 HCl 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



0 36800 37579 6

CODE AREA
• no varnish • no color

18630 88 FL

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TOPCO ASSOCIATES LLC
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QUESTIONS? 1-888-423-0139
topcare@topco.com
www.topcarebrand.com



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

GF GLUTEN FREE

QUALITY GUARANTEED
This TopCare® 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 Vicks® ZzzQuil®.

NDC 36800-200-30



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DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING

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PEEL BACK FOR DRUG FACTS →

ADHESIVE AREA NO COPY

<p>Drug Facts (continued)</p> <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> ■ a breathing problem such as emphysema or chronic bronchitis ■ glaucoma ■ difficulty in urination due to enlargement of the prostate gland <p>Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers</p> <p>When using this product</p> <ul style="list-style-type: none"> ■ avoid alcoholic beverages <p>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.</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p>	<p>Drug Facts (continued)</p> <p>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).</p> <p>Directions</p> <ul style="list-style-type: none"> ■ take only one dose per day (24 hours) ■ only use the dose cup provided <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="padding: 2px;">adults & children 12 yrs & over</td> <td style="padding: 2px;">30 mL at bed time if needed or as directed by a doctor</td> </tr> <tr> <td style="padding: 2px;">children under 12 yrs</td> <td style="padding: 2px;">do not use</td> </tr> </table> <p>Other information</p> <ul style="list-style-type: none"> ■ each 30 mL contains: sodium 20 mg ■ store at 20-25°C (68-77°F) 	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	<p>Drug Facts (continued)</p> <p>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</p> <p>Questions or comments? 1-888-423-0139</p>
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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: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	50 mg 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	
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 final	part338	08/20/2013	

Labeler - Topco Associates LLC (006935977)