

TOPCARE ZZZ SLEEP- diphenhydramine hydrochloride 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 dose cup)

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
- with other drugs that cause drowsiness such as antihistamines and nighttime cold/flu products
- with other Nighttime products

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
- drowsiness will occur
- do not drive a motor vehicle or operate machinery

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.

Overdose warning: Taking more than directed can cause serious health problems. 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) – see Overdose warning
- use dose cup

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 dose cup contains: sodium 20 mg
- store at 20-25°C (68-77°F)
- protect from light. Does not meet USP <671>.

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

NIGHTTIME SLEEP-AID

ZZZ Sleep®

DIPHENHYDRAMINE HCl

50 mg PER 30 mL

Non-habit forming

BERRY FLAVOR

COMPARE TO VICKS® ZzzQuil® active ingredient

ALCOHOL 10%

Not for treating Cold or Flu

See Warnings

6 FL OZ (177 mL)



0 36800 37579 6

GLUTEN FREE



This Top Care® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.

DISTRIBUTED BY
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NDC 36800-200-30

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• Non-habit forming
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DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING

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<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 an 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 ■ drowsiness will occur ■ do not drive a motor vehicle or operate machinery <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>Drug Facts (continued)</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children. Overdose warning: Taking more than directed can cause serious health problems. 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) – see Overdose warning ■ use dose cup <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>	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>Other information</p> <ul style="list-style-type: none"> ■ each 30 mL dose cup contains: sodium 20 mg ■ store at 20-25°C (68-77°F) ■ protect from light. Does not meet USP <671>. <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 LABEL	Item Code (Source)	NDC:36800-200
Route of Administration	ORAL	DEA Schedule	
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DIPHENHYDRAMINE HYDROCHLORIDE (DIPHENHYDRAMINE)	DIPHENHYDRAMINE HYDROCHLORIDE	50 mg in 30 mL	
Inactive Ingredients			
Ingredient Name	Strength		
ALCOHOL			

ANHYDROUS CITRIC ACID	
FD&C BLUE NO. 1	
FD&C RED NO. 40	
HIGH FRUCTOSE CORN SYRUP	
POLOXAMER 407	
PROPYLENE GLYCOL	
WATER	
SACCHARIN SODIUM	
SODIUM BENZOATE	
SODIUM CITRATE	

Product Characteristics

Color	PURPLE (clear)	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		
2	NDC:36800-200-40	355 mL in 1 BOTTLE		
3	NDC:36800-200-34	236 mL in 1 BOTTLE		
4	NDC:36800-200-50	2 in 1 PACKAGE		
4		355 mL in 1 BOTTLE		

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)

Registrant - L. Perrigo Company (006013346)

Establishment

Name	Address	ID/FEI	Business Operations
L. Perrigo Company		006013346	MANUFACTURE(36800-200)