

EQUALINE NIGHT TIME SLEEP AID- diphenhydramine hcl solution
Supervalu 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.

SuperValu Inc. NightTime SleepAid 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 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)
- 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?

1-877-932-7948

Package/Label Principal Display Panel

compare to Vicks® ZzzQuil® active ingredient

nighttime

sleep aid

diphenhydramine HCl

50mg per 30mL

#1 doctor recommended sleep-aid active ingredient

non-habit forming

NOT FOR TREATING COLD OR FLU

berry flavor

ALCOHOL 10%

6 FL OZ (177mL)



0 41163 49535 7

*This product is not manufactured or distributed by Procter & Gamble, distributor of Vicks® ZzzQuil®.

◆Of U.S. physicians surveyed by an independent market research firm.

Distributed by
SUPERVALU INC.
Eden Prairie, MN 55344 USA

100% Quality GUARANTEED

Like it or let us make it right.
That's our quality promise.
877-932-7948
supervaluprivatebrands.com

NDC 41163-186-30

compare to
Vicks® ZzzQuil®
active ingredient*

EQUALINE®

nighttime sleep aid

diphenhydramine HCl
50mg per 30mL

• #1 doctor recommended sleep-aid active ingredient*
• non-habit forming

NOT FOR TREATING COLD OR FLU

berry flavor
ALCOHOL 10% **6 FL OZ (177mL)**

DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING

Drug Facts

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Diphenhydramine HCl 50 mg.....	Nighttime sleep-aid

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PEEL BACK FOR DRUG FACTS →

<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; margin-top: 5px;"> <tr> <td style="width: 30%;">adults & children 12 yrs & over</td> <td style="width: 70%;">30 mL at bed time if needed or as directed by a doctor</td> </tr> <tr> <td>children under 12 yrs</td> <td>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? 1-877-932-7948</p> <p>GLUTEN FREE</p>
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children under 12 yrs	do not use					

EQUALINE NIGHT TIME SLEEP AID			
diphenhydramine hcl solution			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41163-186
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 (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:41163-186-30	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/28/2013	
2	NDC:41163-186-40	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/28/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part338	06/28/2013	

Labeler - Supervalu Inc (006961411)