

GOOD NEIGHBOR PHARMACY SLEEP TIME- diphenhydramine hcl solution
Amerisource Bergen

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.

Amerisource Bergen Sleep Time 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?

1-800-719-9260

Package/Label Principal Display Panel

Compare to Vicks® ZzzQuil® active ingredient

NON-HABIT FORMING

Sleep Time

Diphenhydramine HCl

50 mg per 30 mL

Nighttime Sleep-Aid

Not for treating Cold or Flu

See Warnings

10% ALCOHOL

Berry Flavor

6 fl oz (177 mL)

*Good Neighbor Pharmacy®
Sleep Time is not manufactured or distributed by Procter & Gamble, distributor of Vicks® ZzzQuil®.

GLUTEN FREE

Distributed By AmerisourceBergen
1300 Morris Drive
Chesterbrook, PA 19087
Visit us at
www.goodneighborpharmacy.com

18630 29 F2

Compare to Vicks® ZzzQuil® active ingredient*

NDC 46122-204-30

NON-HABIT FORMING

Sleep Time

Diphenhydramine HCl
50 mg per 30 mL

Nighttime Sleep-Aid

- Not for treating Cold or Flu
- See Warnings

10% ALCOHOL
Berry Flavor

6 fl oz (177 mL)

DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING

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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 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? 1-800-719-9260</p>
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GOOD NEIGHBOR PHARMACY SLEEP TIME			
diphenhydramine hcl solution			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46122-204
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: 059QF0K00R)	
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:46122-204-30	177 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part338	07/22/2013	

Labeler - Amerisource Bergen (007914906)