BERKLEY AND JENSEN SLEEP AID- diphenhydramine hcl solution BJWC

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.

BJWC Sleep-Aid 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?

1-800-BJS-CLUB

Package/Label Principal Display Panel

Compare to the Active Ingredient in Vicks® ZzzQuil®

berkley jensen®

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berkley jensen®

SLEEP-AID

DIPHENHYDRAMINE HCI 50 mg PER 30 mL

NIGHTTIME SLEEP-AID

NON-HABIT FORMING

NOT FOR TREATING COLD OR FLU

10% ALCOHOL

NIGHTTIME SLEEP-AID

SLEEP-AID

DIPHENHYDRAMINE HCI 50 mg PER 30 mL

HELPS YOU FALL ASLEEP • NON-HABIT FORMING

100% MONEY-BACK GUARANTEE

BERRY FLAVOR

THREE 12 FL OZ (355mL) BOTTLES, TOTAL 36 FL OZ (2.25 pt) 1.06L



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A0356 D3 C2



BERKLEY AND JENSEN SLEEP AID

diphenhydramine hcl solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68391-186
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, 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	
NDC:68391-186-	3 in 1 CARTON	07/23/2020		
1	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	07/23/2020	

Labeler - BJWC (159082692)

Revised: 4/2023 BJWC