

**NIGHTTIME SLEEP AID- diphenhydramine hydrochloride capsule, liquid filled
BJWC (Berkley & Jensen / BJ's)**

BJs 613T Diphenhydramine Hydrochloride 25 mg Liquid

Drug Facts

Active ingredient (in each softgel)

Diphenhydramine HCl 25 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 (1-800-222-1222) right away.

Directions

- take only one dose (2 softgels) per day (24 hours)

adults & children 12 yrs & over	2 softgels at bedtime if needed or as directed by a doctor
children under 12 yrs	do not use

Other information

- store at 20-25° C (68-77°F)
- avoid excessive heat above 40°C (104°F)

- protect from light.

Inactive ingredients

FD&C blue no. 1, FD&C red no. 40, gelatin, glycerol, polyethylene glycol 400, propylene glycol, purified water, shellac, sorbitol sorbitan solution, titanium dioxide.

Questions or comments? Call 1-877-290-4008



NIGHTTIME SLEEP AID

diphenhydramine hydrochloride capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68391-613
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)		DIPHENHYDRAMINE HYDROCHLORIDE	25 mg
Inactive Ingredients			
Ingredient Name			Strength
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)			
WATER (UNII: 059QF0KO0R)			
GLYCERIN (UNII: PDC6A3C0OX)			

SORBITAN (UNII: 6O92ICV9RU)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
SHELLAC (UNII: 46N107B71O)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	purple (Purple, Translucent)	Score	no score
Shape	CAPSULE (Oblong shaped)	Size	16mm
Flavor		Imprint Code	121
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68391-613-92	16 in 1 CARTON	08/20/2025	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M010	08/20/2025	

Labeler - BJWC (Berkley & Jensen / BJ's) (159082692)

Registrant - TIME CAP LABORATORIES, INC (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		925822975	manufacture(68391-613)

Revised: 8/2025

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