EZ NITE SLEEP- diphenhyramine hydrochloride capsule, liquid filled KROGER COMPANY

Kroger Diphenhydramine Hydrochloride 25 mg Softgels

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.

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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 ifsleeplessness 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 per day (24 hours)

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

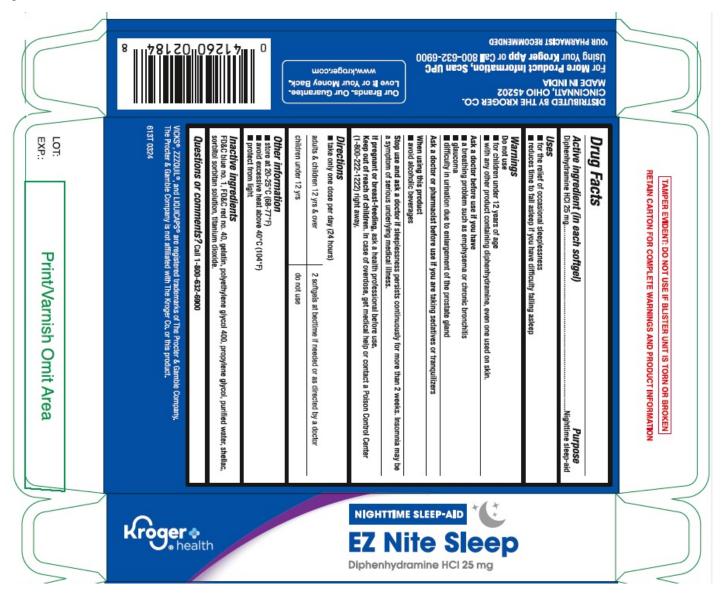
Other information

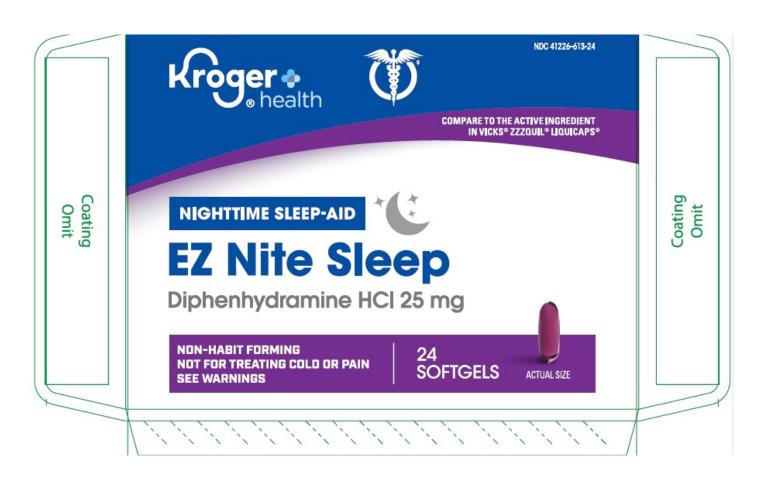
- store at 20-25° C (68-77°F)
- avoid excessive heat above 40°C (104°F)
- protect from light

Inactive ingredients

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

Questions or comments? Call 1-800-632-6900





EZ NITE SLEEP

diphenhyramine hydrochloride capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41226-613
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Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients	
Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SHELLAC (UNII: 46N107B710)	
WATER (UNII: 059QF0KO0R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

SORBITAN	(UNII)	6092ICV9RU)	
JUNDITAR	OIVII.	003210431107	

Product Characteristics				
Color	purple (Purple,translucent)	Score	no score	
Shape	CAPSULE (oblong shaped)	Size	16mm	
Flavor		Imprint Code	121	
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:41226- 613-24	2 in 1 CARTON	04/15/2024		
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	04/15/2024	

Labeler - KROGER COMPANY (006999528)

Registrant - TIME CAP LABORATORIES, INC (037052099)

Establishment				
Name	Address	ID/FEI	Business Operations	
MARKSANS PHARMA LIMITED		925822975	manufacture(41226-613)	

Revised: 4/2024 KROGER COMPANY