NIGHT TIME SLEEP AID- diphenhydramine hydrochloride capsule, liquid filled PuraCap Pharmaceutical LLC

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.

Night Time Sleep Aid

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
- with other drugs that cause drowsiness such as antihistamines and nighttime cold/flu products

Ask a doctor before use if you have

- a breathing problem such as asthma, emphysema, or chronic bronchitis
- glaucoma
- difficulty in urination due to enlargement of the prostate gland
- heart disease

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers or any other sleep aid

When using this product

- avoid alcoholic beverages and other drugs that cause drowsiness
- drowsiness will occur
- be careful when driving a motor vehicle or operating 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.

Directions

• take only one dose per day (24 hours) - see **Overdose warning**

adults and children 12 years and over ONE dose = TWO 25 mg softgels (50 mg) at bed time if needed or as directed by a doctor

Other Information

- store at 15-30° C (59-86° F)
- avoid excessive heat above 40° C (104° F) and high humidity
- protect from light

Inactive ingredients

FD&C blue #1, FD&C red #40, gelatin, glycerin, polyethylene glycol, purified water, sorbitol special, and white edible ink

Questions or comments?

Call toll free **1-888-309-9030**

PRINCIPAL DISPLAY PANEL - Carton Label

Night Time Sleep-Aid

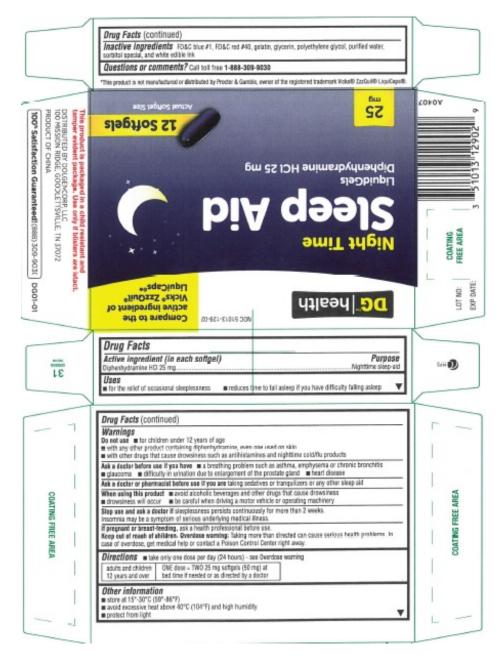
Diphenhydramine HCl, 25 mg

Compare to the active ingredient of Vicks[®] ZzzQuil[®] LiquiCaps^{®*}

12 Softgels

NDC 51013-129-02

*This product is not manufactured or distributed by Procter & Gamble, owner of the registered trademark Vicks® ZzzQuil[®] LiquiCaps[®].



NIGHT TIME SLEEP AI	D								
diphenhydramine hydrochloride capsule, liquid filled									
Product Information									
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:51013-129					
Route of Administration	ORAL								
Active Ingredient/Active Moiety									
Ingredient Name			Basis of Strength		Strength				
DIPHENHYDRAMINE HYDRO CHLO RIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)			DIPHENHYDRAMINE HYDROCHLORIDE		25 mg				
Inactive Ingredients									

Ingredient Name									
FI	FD&C BLUE NO. 1 (UNII: H3R47K3TBD)								
FI	FD&C RED NO. 40 (UNII: WZB9127XOA)								
GELATIN (UNII: 2G86QN327L)									
GLYCERIN (UNII: PDC6A3C0OX)									
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)									
WATER (UNII: 059QF0KO0R)									
so	RBITOL (UNII: 50	6T60A25R)							
P 1	roduct Charact	eristics							
Color		purple	Score		no score				
Sł	ape	capsule (oblong) Size		14mm					
Fl	avor		Imprint (Code	PC11				
Contains									
Pa	ackaging								
#	Item Code	Package Description	Package Description		Marketing End Date				
1	NDC:51013-129-02	1 in 1 CARTON	1 CARTON						
1		12 in 1 BLISTER PACK; Type 0: Not a Combina	1 BLISTER PACK; Type 0: Not a Combination Product						
Marketing Information									
	Marketing Category Application Number or Monograph Citation		Marketing Start Date	Marketing End Date					
			05/05/2016	Line ung Line Dute					
0.	C monograph mai	Purioso		00/00/2010					

Labeler - PuraCap Pharmaceutical LLC (962106329)

Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd		421293287	manufacture(51013-129), analysis(51013-129)

Revised: 11/2019

PuraCap Pharmaceutical LLC