

**MAXIMUM STRENGTH NIGHTTIME 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.*

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**MAXIMUM STRENGTH Nighttime Sleep-Aid**

**Drug Facts**

**Active ingredient (in each softgel)**

Diphenhydramine HCl 50 mg

**Purpose**

Nighttime sleep-aid

**Use**

- for relief of occasional sleeplessness

**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
- trouble urinating due to an enlarged prostate gland

**Ask a doctor or pharmacist before use if you are** taking sedatives or tranquilizers

**When using this product** avoid alcoholic drinks

**Stop use and ask a doctor if** sleeplessness persist 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.

**Directions**

- adults and children 12 years of age and over: 1 softgel (50 mg) at bedtime if needed, or as directed by a doctor

## Other information

- Store at room temperature 15°-30°C (59°-86°F) and avoid excessive heat
- do not use if imprinted safety seal under cap is broken or missing

## Inactive ingredients

FD&C blue #1, gelatin, glycerin, polyethylene glycol, purified water, sorbitol sorbitan solution and white ink

## Questions or comments?

Call toll free: 1-855-215-8180

## PRINCIPAL DISPLAY PANEL

MAXIMUM STRENGTH Nighttime Sleep-Aid

200 SOFTGELS

NDC 51013-420-38

\*Compare to the active ingredient in Unisom® SleepGels®

## MAXIMUM STRENGTH NIGHTTIME SLEEP AID

diphenhydramine hydrochloride capsule, liquid filled

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51013-420
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

## Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	

## Product Characteristics

Color	blue (clear)	Score	no score
Shape	capsule (oval)	Size	14mm
Flavor		Imprint Code	PC5
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51013-420-38	200 in 1 BOTTLE; Type 0: Not a Combination Product	09/25/2017	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part338	09/25/2017	

**Labeler** - PuraCap Pharmaceutical LLC (962106329)

## Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd		421293287	manufacture(51013-420) , analysis(51013-420)

Revised: 1/2020

PuraCap Pharmaceutical LLC