

NIGHTTIME SLEEP AID- diphenhydramine capsule, liquid filled

Velocity Pharma

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.

DIPHENHYDRAMINE HCl 50mg, USP

Active Ingredient

(in each softgel)

Diphenhydramine HCl 50 mg

Purpose

Nighttime sleep aid

Uses

- For relief of occasional sleeplessness.

Directions

- **adults and children 12 years and over** : one softgel (50 mg) at bed time if needed or as directed by a doctor.
- **children under 12 years:do not use**

Warnings

Do not use

- in 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

- glaucoma
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis

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

When using this product

- avoid alcoholic drinks

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)

Other Information

- save carton for full directions and warnings

Inactive Ingredients

Blue 1, gelatin, glycerin, polyethylene glycol, polyvinyl acetate phthalate, propylene glycol, sorbitol,

titanium dioxide and water.

Questions or Comments

Call 1-855-314-1850

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

0995

1.625

4.625

NDC 076168-065-37

Night Time

Sleep Aid

SOFTGEL CAPSULES

DIPHENHYDRAMINE HCl SOFT GEL CAPSULES
NIGHTTIME SLEEP AID

16

SOFTGELS



LIQUID FILLED

50mg Diphenhydramine per Soft Gel

Active ingredient Purpose (in each softgel)

Diphenhydramine Nighttime sleep aid
HCl 50mg

Use

For relief of occasional sleeplessness.

Directions

Adults and children 12 years and over:

- One softgel (50 mg) at bedtime if needed, or as directed by a doctor.

Children under 12 years: do not use

Warnings

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Do not use:

- In children under 12 years of age.
- With any other product containing diphenhydramine, even one used on skin.

Inactive Ingredients

Blue 1, gelatin, glycerin, polyethylene glycol, polyvinyl acetate phthalate, propylene glycol, sorbitol, titanium dioxide and water.

Questions or comments?
Call: 1-855-314-1850

Distributed by **VELOCITY PHARMA LLC**
226 B Sherwood Avenue, Farmingdale, NY 11735

VELUNI16CTL



DIPHENHYDRAMINE HYDROCHLORIDE SOFTGEL CAPSULE, USP 50 MG
NDC:76168-065-37 16 Softgel Liquid filled

NIGHTTIME SLEEP AID

diphenhydramine capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76 168-065
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: HBR47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	
SORBITOL (UNII: 506T60A25R)	
POLYVINYL ACETATE PHTHALATE (UNII: 58QVG85GW3)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	blue	Score	no score
Shape	OVAL	Size	16mm
Flavor		Imprint Code	206
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76168-065-37	16 in 1 BOTTLE	03/31/2014	
1		1 in 1 CARTON; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/31/2014	

Labeler - Velocity Pharma (962198409)**Registrant** - Velocity Pharma (962198409)