NIGHT TIME SLEEP AID- diphenhydramine hcl capsule Hy-Vee

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.

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 persists continuously for more than 2 weeks. Insomnia may be a symptom of a 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 15°-30°C (59°-86°F)

Inactive ingredients

edible white ink, FD&C blue #1, gelatin, glycerin, light mineral oil*, polyethylene glycol, purified water, sorbitol-sorbitan

*may contain this ingredient

Questions or comments?

Call toll free 1-800-289-8343 Monday-Friday 9AM-4PM CST

Principal Display Panel

†Compare to the Active Ingredient of Unisom® SleepGels®

Maximum Strength

Night Time Sleep Aid

DIPHENHYDRAMINE HCl, 50 mg

Safe, Non-Habit Forming

- Fall Asleep Fast
- Sleep Soundly
- Wake up Refreshed

SOFTGELS**

(**LIQUID FILLED)

†This product is not manufactured or distributed by Chattem, Inc., owner of the registered trademark Unisom® SleepGels®.

DISTRIBUTED BY HY-VEE, INC.

5820 WESTOWN PARKWAY

WEST DES MOINES, IA 50266

www.hy-vee.com

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

Package Label



Hy-Vee Health Maximum Strength NightTime Sleep Aid

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Purpose

■ for children under 12 years of age ■ with any other product containing diphenhydramine, even one used on skin

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USO for relief of occasional sleeplessness.

Active ingredient (in each sortgel)

Оірһепһуагатіпе НСІ 50 тд.

Warnings

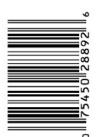
Drug Facts

NIGHT TIME SLEEP AID

diphenhydramine hcl capsule

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42507-236
Route of Administration	ORAL		

Active Ingredient/Active Moiety



Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDRO CHLO RIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE -		50 mg
UNII:8GTS82S83M)	HYDROCHLORIDE	50 mg

Inactive Ingredients		
Ingredient Name	Strength	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
GELATIN (UNII: 2G86QN327L)		
GLYCERIN (UNII: PDC6 A3C0 OX)		
LIGHT MINERAL OIL (UNII: N6K5787QVP)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
WATER (UNII: 059QF0KO0R)		
SORBITAN (UNII: 6O92ICV9RU)		
SORBITOL (UNII: 506T60A25R)		

Product Characteristics				
Color	BLUE	Score	no score	
Shape	CAPSULE	Size	13mm	
Flavor		Imprint Code	P50;A99;S90	
Contains				

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42507-236- 32	1 in 1 BOX	0 2/0 1/20 14	
1		32 in 1 BOTTLE, PLASTIC; 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	0 2/0 1/20 14		

Labeler - Hy-Vee (006925671)

Revised: 12/2019 Hy-Vee