SLEEP AID MAXIMUM STRENGTH- diphenhydramine hcl capsule P & L Development, LLC

Drug Facts

Active ingredient (in each softgel)

Diphenhydramine HCL 50 mg

Purpose

Nighttime sleep-aid

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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 (1-800-222-1222)

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 between 15°-30°C (59°-86°F)

Inactive ingredients

FD&C blue #1, gelatin, glycerin, lecithin, light mineral oil, mannitol, polyethylene glycol, propylene, purified water, sorbitol, sorbitan, white ink

Questions or comments?

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

Principal Display Panel

Maximum Strength

Sleep-Aid

diphenhydramine HCl 50 mg

nighttime sleep-aid

safe, non-habit forming

softgels

One Softgel Per Dose

†Compare to the active ingredient in Unisom® SleepGels®

†This product is not manufactured or distributed by Chattem, Inc., distributor of Unisom® SleepGels®.

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

Distributed by: **PL Developments**

200 Hicks Street

Westbury, NY 11590

Package Label

WELLNESS BASICS Maximum Strength Sleep Aid

SLEEP AID MAXIMUM STRENGTH

diphenhydramine hcl capsule

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:59726-816

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength

DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6|AD40)

DIPHENHYDRAMINE

DIDHENHYDDAMINE LINII: 9GTS 82S 83M)

(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)

LECITHIN, SOYBEAN (UNII: 1DI56QDM62)

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3MJQ0SDW1A)

WATER (UNII: 059QF0KOOR)
SORBITAN (UNII: 6092ICV9RU)
SORBITOL (UNII: 506T60A25R)

LIGHT MINERAL OIL (UNII: N6K5787QVP)

MANNITOL (UNII: 30WL53L36A)

Product Characteristics

Color	blue	Score	no score	
Shape	CAPSULE	Size	13mm	
Flavor		Imprint Code	PC5	
Contains				

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:59726- 816-92	96 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/29/2019			
2	NDC:59726- 816-64	1 in 1 BOX	11/29/2019			
2		64 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product				
3	NDC:59726- 816-29	2 in 1 BOX	11/29/2019			
3		96 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product				

Marketing Information					
Marketing Category			Marketing End Date		
OTC Monograph Drug	M012	11/29/2019			

Labeler - P & L Development, LLC (800014821)

Revised: 10/2023 P & L Development, LLC