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

Drug Facts

Active ingredient (in each softgel)

Diphenhydramine HCI 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, polyethylene glycol, 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

†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

1 Todace Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59726-760

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)				
SORBITAN (UNII: 6O92ICV9RU)				
SORBITOL (UNII: 506T60A25R)				

Product Characteristics				
Color	blue	Score	no score	
Shape	CAPSULE	Size	13mm	
Flavor		Imprint Code	P50	
Contains				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59726- 760-92	96 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/29/2019	

2	NDC:59726- 760-64	1 in 1 BOX	11/29/2019	
2		64 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:59726- 760-29	2 in 1 BOX	11/29/2019	
3		96 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 Drug	M012	11/29/2019	

Labeler - P & L Development, LLC (800014821)

Revised: 10/2023 P & L Development, LLC