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

Drug Facts

Active ingredient (in each softgel)

Diphenhydramine HCl 50 mg

Purpose

Nighttime sleep-aid

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

Principal Display Panel

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

Maximum Strength

Nighttime Sleep-Aid

Diphenhydramine HCl 50 mg

safe, non-habit forming

- Fall Asleep Fast
- Sleep Soundly
- Wake up Refreshed

SOFTGELS Liquid Filled

One Softgel Per Dose

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

Distributed by:

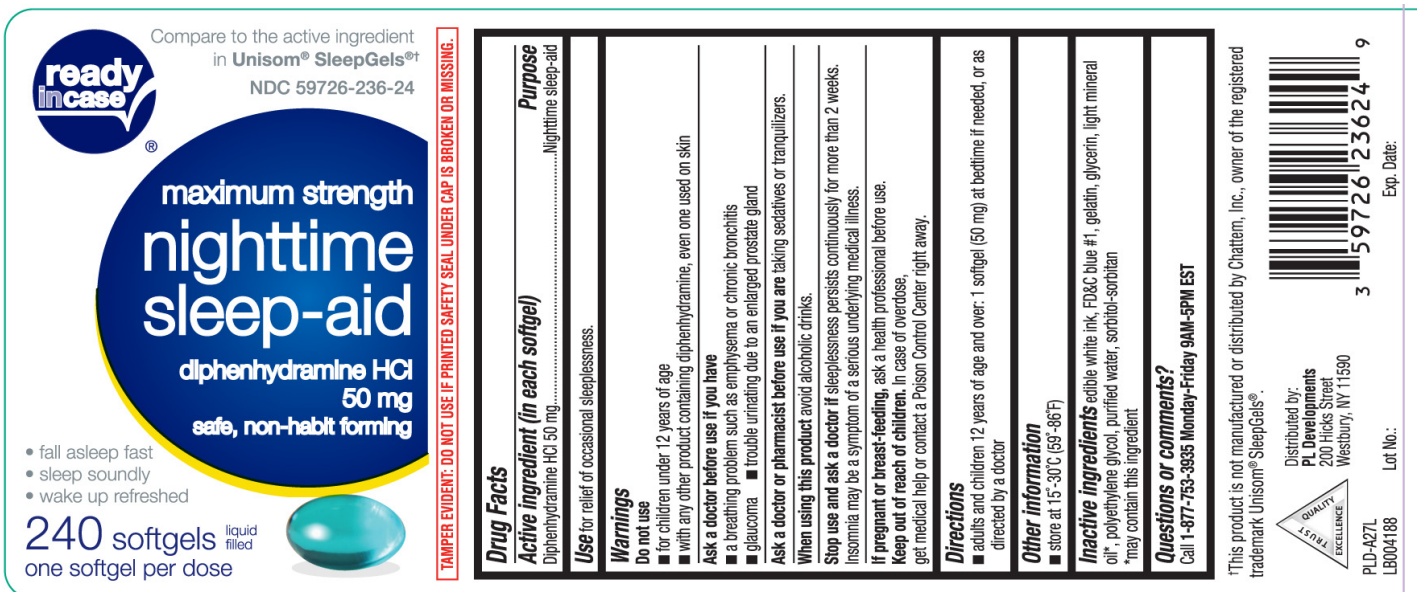
PL Developments

200 Hicks Street

Westbury, NY 11590

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

Package Label



ReadyinCase Nighttime sleep-aid maximum strength

SLEEP AID MAXIMUM STRENGTH

diphenhydramine hcl capsule

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59726-236
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)	
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			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59726-236-08	1 in 1 CARTON	02/01/2014	
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:59726-236-32	1 in 1 BOX	02/01/2014	
2		32 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:59726-236-24	240 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	02/01/2014	

Labeler - P & L Development, LLC (800014821)

Revised: 12/2019 P & L Development, LLC