

**SLEEP AID MAXIMUM STRENGTH- diphenhydramine hcl capsule
QUALITY CHOICE (Chain Drug Marketing Association)**

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

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

Ask a doctor before use if

- 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

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

*contains one or more of these ingredients

Questions or comments?

Call **1-248-449-9300** Monday-Friday 9AM-5PM EST

Principal Display Panel

†Compare to the Active Ingredient in Unisom® SleepGels®

Sleep-Aid Maximum Strength

Nighttime Sleep-Aid

Diphenhydramine HCl, 50 mg

Help to Reduce Difficulty Falling Asleep

Softgels

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

**TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAPIS
BROKEN OR MISSING.**

**KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT
INFORMATION.**

Distributed by C.D.M.A., Inc. ©

43157 W 9 Mile Rd

Novi, MI 48375

www.qualitychoice.com

Product Label



NDC 63868-394-32

† Compare to the Active Ingredient in Unisom® SleepGels®

Sleep-Aid Maximum Strength

Nighttime Sleep-Aid

Diphenhydramine HCl 50 mg
Helps To Reduce Difficulty Falling Asleep



32 Softgels

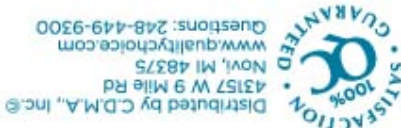
actual size



Lot No.:
Exp. Date:

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.
KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

PLD-F270
FC005241



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

Drug Facts
Active ingredient (in each softgel) Diphenhydramine HCl 50 mg.....Nighttime sleep-aid
Use For relief of occasional sleeplessness.
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 ■ 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 edible white ink, FD&C blue #1, gelatin, glycerin, glycerol, polyethylene glycol, propylene glycol, purified water, sorbitan, sorbitol *contains one or more of these ingredients
Questions or comments? Call 1-248-449-9300 Monday-Friday 9AM-5PM EST

QUALITY CHOICE Nighttime Sleep-Aid

SLEEP AID MAXIMUM STRENGTH

diphenhydramine hcl capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-394
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: 059QF0K00R)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Product Characteristics

Color	blue	Score	no score
Shape	CAPSULE	Size	13mm
Flavor		Imprint Code	P50;A99;D50;AP018
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-394-32	1 in 1 BOX	08/31/2018	12/27/2024
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	part338	08/31/2018	12/27/2024

Revised: 9/2022

QUALITY CHOICE (Chain Drug Marketing Association)