

PREMIER VALUE SLEEP-AID - diphenhydramine hcl capsule
Chain Drug Consortium 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.

ACTIVE INGREDIENT(S)

Diphenhydramine HCl 50 mg

PURPOSE

Nighttime sleep- aid

USE(S)

- helps to reduce difficulty falling asleep

WARNINGS

Do not give to children under 12 years of age.

DO NOT USE

- With other products containing diphenhydramine, even one used on skin.

ASK A DOCTOR BEFORE USE IF

- emphysema
- chronic bronchitis
- glaucoma
- difficulty in urination due to an enlargement of the prostate gland

ASK A DOCTOR OR PHARMACIST BEFORE USE IF

Sedatives or tranquilizers

WHEN USING THIS PRODUCT

Avoid alcoholic beverages

STOP USE AND ASK DOCTOR IF

- Sleeplessness persists for more than 2 weeks. Insomnia may be a symptom of a serious underlying medical illness.

PREGNANCY/BREASTFEEDING

Ask a health professional before use.

KEEP OUT OF REACH OF CHILDREN

In case of accidental 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:** take 1 softgel at bedtime if needed or as directed by a doctor

STORAGE

- Store at controlled room temperature 15°-30°C (59°-86°F)
- do not use if imprinted safety seal under cap is broken or missing
- *This product is not manufactured or distributed by Chattem, Inc., owner of the registered trademark Maximum Strength Unisom SleepGels®

INACTIVE INGREDIENTS

Gelatin, Sorbitol, Sorbitan, FD&C Blue No. 1, Water, Polyethylene Glycol 400, Povidone K-30

PRINCIPAL DISPLAY PANEL

Carton Label PDP

NDC # 68016-302-32

Sleep-Aid

DIPHENHYDRAMINE HCL 50 mg

GET TO SLEEP FAST

SLEEP SOUNDLY

WAKE REFRESHED

32 Softgels



Premier Value

SAFE AND NON-HABIT FORMING FOR RESTORATIVE SLEEP

Premier Value

COMPARE TO THE ACTIVE INGREDIENT IN UNISOM® SLEEPGELS®

Sleep-Aid

- GET TO SLEEP FAST
- SLEEP SOUNDLY
- WAKE REFRESHED

DIPHENHYDRAMINE HCl 50 mg

32 Softgels*

32 Softgels*
DIPHENHYDRAMINE HCl 50 mg
Sleep-Aid

Premier Value

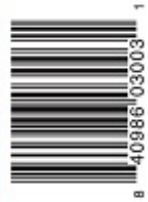
COMPARE TO THE ACTIVE INGREDIENT IN UNISOM® SLEEPGELS®

Sleep-Aid

- GET TO SLEEP FAST
- SLEEP SOUNDLY
- WAKE REFRESHED

DIPHENHYDRAMINE HCl 50 mg

32 Softgels*



LOT: EXP:

DISTRIBUTED BY: CHAIN DRUG CONSORTIUM, LLC
3301 BOCA RATON BLVD, SUITE 101 BOCA RATON, FL 33431
If for any reason you are not satisfied with this product, please return it to the store where purchased for a full refund.

<p>Drug Facts</p> <p>Active ingredient (in each softgel) Diphenhydramine HCl 50 mg. <i>Nighttime sleep-aid.</i></p> <p>Purpose If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)</p> <p>Directions Take 1 softgel at bedtime if needed or as directed. Adults and children 12 years of age and over.</p> <p>Other information Store at controlled room temperature (15°-30°C (59°-86°F)). Do not use if printed safety seal under cap is broken or missing.</p> <p>Inactive ingredients Each hard gel, FD&C Blue #1, gelatin, polyethylene glycol, povidone, purified water and sodium hydroxide.</p> <p><small>*This product is not manufactured or distributed by Chasman, Inc., owner of the registered trademark Unisom Sleepgels. However, Unisom Sleepgels® is a trademark of Chasman, Inc.</small></p>	<p>Warnings Do not use this product with other products containing diphenhydramine, even one used on skin.</p> <p>Ask a doctor before use if you have: • asthma • chronic bronchitis • emphysema • difficulty in urination due to an enlarged prostate gland</p> <p>Ask doctor or pharmacist before use if you are: • taking medicine for high blood pressure, heart disease, or other conditions • taking alcohol, grapefruit juice, or other products that may interact with this medicine</p> <p>Stop use and ask a doctor if: • symptoms persist for more than 2 weeks. • you experience dizziness, lightheadedness, or other symptoms.</p> <p>Contains 32 softgels. Each softgel contains 50 mg of diphenhydramine HCl.</p>
--	---

KEEP OUT OF REACH OF CHILDREN FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

NDC # 68016-302-32

Sleep-Aid
DIPHENHYDRAMINE HCL 50 mg

GET TO SLEEP FAST
SLEEP SOUNDLY
WAKE REFRESHED

32 Softgels

PREMIER VALUE SLEEP-AID

diphenhydramine hcl capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68016-302
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)	
WATER (UNII: 059QF0K00R)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE K30 (UNII: U725QWY32X)	

Product Characteristics

Color	BLUE	Score	no score
Shape	CAPSULE	Size	13mm
Flavor		Imprint Code	22
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-302-32	1 in 1 CARTON		
1		32 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	05/31/2013	

Labeler - Chain Drug Consortium LLC (101668460)**Registrant** - Chain Drug Consortium LLC (101668460)**Establishment**

Name	Address	ID/FEI	Business Operations
Marksans Pharma Limited		925822975	MANUFACTURE(68016-302)

Revised: 5/2013

Chain Drug Consortium LLC