

MAXIMUM STRENGTH SLEEP AID- diphenhydramine hcl capsule, gelatin coated
KROGER COMPANY

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.

Kroger® MAXIMUM STRENGTH Sleep Aid Softgels

Drug Facts

Active ingredient (in each softgel)

Diphenhydramine HCl 50 mg

Purpose

Nighttime sleep-aid

Use

for the 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 persist continuously for more than 2 weeks. Insomnia may be a symptom of 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

Inactive ingredients

FD&C Blue#1, gelatin, glycerin, polyethylene glycol-400, propylene glycol, sorbitol, titanium dioxide, water

Questions or comments?

1-800-632-6900

DISTRIBUTED BY THE KROGER CO.
CINCINNATI, OHIO 45202

GLUTEN FREE

PRINCIPAL DISPLAY PANEL

COMPARE TO the active ingredient of
UNISOM® SLEEPGELS®**

NDC 30142-228-32

NDC 30142-228-40

NDC 30142-228-64

Kroger®

Sleep-Aid Softgels
MAXIMUM STRENGTH

Diphenhydramine HCl 50 mg

Nighttime Sleep Aid
Safe, Non-Habit Forming

32/40/64

LIQUID FILLED SOFTGELS one softgel per dose

actual size

**Unisom® SleepGels® is a registered trademark of Chattem, Inc., Chattanooga, TN 37409. Chattem, Inc., is not affiliated with The Kroger Co. or this product.



Drug Facts
Active ingredient
 Diphenhydramine HCl 50 mg
 Each softgel contains 50 mg of Diphenhydramine HCl.
Purpose
 Nighttime sleep-aid.
Warnings
 Do not use:
 • If you are under 12 years of age.
 • If you are taking any other sedating drugs, including antihistamines, tranquilizers, or pain relievers.
 • If you have any of the following conditions:
 - glaucoma
 - narrow-angle glaucoma
 - obstructive pulmonary disease
 - stomach or intestinal problems
 - urinary problems
 - prostate problems
 - recent use of MAO inhibitors
 • If you are taking any of the following drugs:
 - alcohol
 - benzodiazepines
 - barbiturates
 - sedatives or tranquilizers
 • If you are pregnant, planning to get pregnant, or breastfeeding.
Directions
 Take 1 softgel at bedtime as directed.
Other information
 • Keep out of reach of children.
 • In case of overdose, get medical help or contact a Poison Control Center right away. (800) 422-1222.

COMPARE TO the active ingredient of
UNISOM® SLEEPGELS®**
Kroger
MAXIMUM STRENGTH
Sleep-Aid Softgels
 Diphenhydramine HCl 50 mg
 Nighttime Sleep Aid
 Safe, Non-Habit Forming
32 LIQUID FILLED SOFTGELS one softgel per dose
 actual size
 U.S. Pharmacopeia
 Verified
 NDC 30142-228-32

COMPARE TO the active ingredient of
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MAXIMUM STRENGTH
Sleep-Aid Softgels
 Diphenhydramine HCl 50 mg
 Nighttime Sleep Aid
 Safe, Non-Habit Forming
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 NDC 30142-228-32

Drug Facts (continued)
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LOT:
 EXP:
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UNISOM and SLEEPGELS are not intended to be used for the treatment of depression.

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 CINCINNATI, OHIO 45202
QUALITY GUARANTEE
 www.kroger.com
 MADE IN INDIA
GLUTEN FREE

01618219



MAXIMUM STRENGTH SLEEP AID

diphenhydramine hcl capsule, gelatin coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30142-228
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	50 mg
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Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B6978945GQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Product Characteristics

Color	blue	Score	no score
Shape	OVAL (903)	Size	13mm
Flavor		Imprint Code	206
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30142-228-32	1 in 1 CARTON	04/17/2019	
1		32 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:30142-228-40	1 in 1 CARTON	04/17/2019	
2		40 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:30142-228-64	1 in 1 CARTON	04/17/2019	
3		64 in 1 BOTTLE; 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	04/17/2019	

Labeler - KROGER COMPANY (006999528)