REST SIMPLY- diphenhydramine hcl tablet, film coated GREAT LAKES WHOLESALE, MARKETING, & SALES, INC.

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.

Healthcare 44-367

Active ingredient (in each caplet)

Diphenhydramine HCl 25 mg

Purpose

Nighttime sleep-aid

Uses

- for relief of occasional sleeplessness
- reduces time to fall asleep if you have difficulty falling asleep

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
- difficulty in urination due to enlargement of the prostate gland
- glaucoma

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers.

When using this product

avoid alcoholic beverages

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

- do not take more than directed
- adults and children 12 years and over: take 2 caplets at bedtime if needed or as directed by a doctor
- children under 12 years: do not use

Other information

- each caplet contains: calcium 30 mg
- TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN
- protect from moisture
- store 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

Inactive ingredients

corn starch, dibasic calcium phosphate dihydrate, FD&C blue #1 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, silicon dioxide, stearic acid, talc, titanium dioxide

Questions or comments?

Call 1-800-426-9391

Principal Display Panel

HEALTHCARE_{TM}

NDC 64092-012-24

*Compare to the active ingredient in Simply Sleep®

Rest Simply

Diphenhydramine Hydrochloride 25 mg

Night Time Sleep Aid

For relief of occasional sleeplessness

- non habit forming
- contains no pain reliever

24 CAPLETS

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

*This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Simply Sleep®.

50844 REV1019E36708

Distributed by: Great Lakes Wholesale & Marketing L.L.C. 3729 Patterson Ave., S.E., Grand Rapids, MI 49512 www.glwholesale.com

HEALTHCARE GUARANTEE

If you are not completely satisfied with this product, regardless of reason, return your unused portion to Great Lakes Wholesale for a full refund

No print/No varnish Lot & Exp date

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24

NDC 64092-012-24

*Compare to the active ingredient in Simply Sleep®

Rest Simpl

Diphenhydramine Hydrochloride 25 mg

Night Time Sleep Aid

For relief of occasional sleeplessness

- non habit forming
- contains no pain reliever

ACTUAL SIZE



24 CAPLETS

portion to Great Lakes Wholesale for a full refund product, regardless of reason, return your unused If you are not completely satisfied with this НЕАГТНСАВЕ GUARANTEE



www.glwholesale.com

Simply Sleep®. 50844 REV1019E36708 & Johnson Corporation, owner of the registered trademark "This product is not manufactured or distributed by Johnson

Questions or comments? Call 1-800-426-9391

polyvinyl alcohol, silicon dioxide, stearic acid, talc, titanium stearate, microcrystalline cellulose, polyethylene glycol, phosphate dihydrate, FD&C blue #1 aluminum lake, magnesium Inactive ingredients corn starch, dibasic calcium

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When using this product avoid alcoholic beverages.

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Do not use *SprinteW*

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. gm 2S IOH ənimsıbydnədqiQ Vighttime sleep-aid Purpose Active ingredient (in each caplet)

REV1019E36708 B-0616-367-08

TAMPER EVIDENT: DO NOT
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Distributed by: Great Lakes Wholesale & Marketing L.L.C. 3729 Patterson Ave., S.E., Grand Rapids, MI 49512

Healthcare 44-367

REST SIMPLY

diphenhydramine hcl tablet, film coated

Product Informa	ation
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Product Type HUMAN OTC DRUG Item Code (Source) NDC:64092-012

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength DIPHENHYDRAMINE HYDRO CHLO RIDE (UNII: TC2D6 JAD40) (DIPHENHYDRAMINE - DIPHENHYDRAMINE 25 mg

UNII:8GTS82S83M) HYDROCHLORIDE

Inactive Ingredients

Ingredient Name		
	ED&C RI HE NO 1 (UNII: H3P47K3TRD)	

MAGNESIUM STEARATE (UNII: 70097M6I30)

CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)

STEARIC ACID (UNII: 4ELV7Z65AP)

TALC (UNII: 7SEV7J4R1U)

TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)

STARCH, CORN (UNII: O8232NY3SJ)

SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)

ANHYDRO US DIBASIC CALCIUM PHO SPHATE (UNII: L11K75P92J)

POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)

Product Characteristics

Color	BLUE	Score	no score	
Shape	OVAL	Size	11mm	
Flavor		Imprint Code	44;367	
Contains				

ı	Packaging							
ı	#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
ı	1	NDC:64092-012-24	2 in 1 CARTON	06/10/2000				
l	1		12 in 1 BLISTER PACK; 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	06/10/2000			

Labeler - Great Lakes wholesale, Marketing, & Sales, Inc. (361925498)

Establishment					
Name	Address	ID/FEI	Business Operations		
LNK International, Inc.		832867894	MANUFACTURE(64092-012)		

Establishment					
Name	Address	ID/FEI	Business Operations		
LNK International, Inc.		038154464	PACK(64092-012)		

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	MANUFACTURE(64092-012), PACK(64092-012)

Establishment					
Name	Address	ID/FEI	Business Operations		
LNK International, Inc.		832867837	PACK(64092-012)		

Establishment					
Name	Address	ID/FEI	Business Operations		
LNK International, Inc.		967626305	PACK(64092-012)		

Revised: 12/2019 GREAT LAKES WHOLESALE, MARKETING, & SALES, INC.