

**SLEEP AID MAXIMUM STRENGTH- diphenhydramine hcl capsule, liquid filled
GREENBRIER INTERNATIONAL, 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.

Assured 44-656-Delisted

Active ingredient (in each liquid-filled capsule)

Diphenhydramine HCl 50 mg

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

- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- difficulty in urination due to enlargement of the prostate gland

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 (1-800-222-1222) right away.

Directions

- **adults and children 12 years and over:** 1 capsule (50 mg) at bedtime if needed, or as directed by a

doctor

Other information

- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- avoid excessive heat
- see end flap for expiration date and lot number

Inactive ingredients

edible white ink, FD&C blue #1, gelatin, glycerin, lecithin, mineral oil, polyethylene glycol, purified water, sorbitol

Questions or comments?

1-800-426-9391

Principal display panel

ASSURED™

**COMPARE TO ACTIVE INGREDIENT OF
UNISOM® SLEEPGELS®***

MAXIMUM STRENGTH

Sleep Aid

- Diphenhydramine HCl 50 mg
Nighttime Sleep-Aid

*Helps reduce difficulty falling asleep
Fast acting, Non-habit forming*

Actual Size

8 softgels

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

ITEM # 934526

DISTRIBUTED BY

GREENBRIER INTERNATIONAL, INC.

500 VOLVO PARKWAY, CHESAPEAKE, VA 23320

*This product is not manufactured or distributed by
Chattem, Inc., owner of the registered trademark
Unisom® SleepGels®. 50844 REV0315A65619

Product of China

Packaged and Quality Assured in the USA

MAXIMUM STRENGTH

ASSURED

Sleep Aid

8 softgels

ASSURED

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Assured 44-656

SLEEP AID MAXIMUM STRENGTH

diphenhydramine hcl capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:33992-0656
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, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	

Product Characteristics

Color	BLUE (clear)	Score	no score
Shape	OVAL	Size	13mm
Flavor		Imprint Code	656
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:33992-0656-9	1 in 1 CARTON	03/01/2015	10/29/2022

1	8 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	03/01/2015	10/29/2022

Labeler - GREENBRIER INTERNATIONAL, INC. (610322518)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(33992-0656)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(33992-0656)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(33992-0656)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(33992-0656)

Revised: 11/2019

GREENBRIER INTERNATIONAL, INC.