

**SLEEP AID NIGHTTIME- diphenhydramine hcl tablet, film coated
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 44-367

Active ingredient (in each caplet)

Diphenhydramine HCl 25 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 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

- use caution when driving a motor vehicle or operating machinery
- drowsiness will occur
- 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

- **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 at 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, dicalcium phosphate, FD&C blue #1 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, silica gel, stearic acid, talc, titanium dioxide

Questions or comments?

1-800-426-9391

Principal Display Panel

ASSURED™

**COMPARE TO ACTIVE INGREDIENT OF
SIMPLY SLEEP®***

Sleep Aid

- **Diphenhydramine HCl 25 mg**
Nighttime sleep-aid

Does not contain Pain Reliever

Non-habit forming

Actual Size

36 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 REV0516E36707

ITEM# 165282

Distributed by: **Greenbrier International, Inc.**
Chesapeake, VA 23320 USA

Sleep Aid

Diphenhydramine HCl 25 mg
Nighttime Sleep-Aid

ASSURED™

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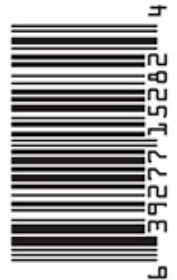
ASSURED™

Sleep Aid

ASSURED™

36 caplets

COMPARE TO ACTIVE INGREDIENT OF
SIMPLY SLEEP®*



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No print/No varnish
Lot & Exp date

Drug Facts

KEEP OUTER PACKAGE FOR
COMPLETE PRODUCT INFORMATION

Active ingredient (in each caplet) Purpose
Diphenhydramine HCl 25 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

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

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machinery ■ drowsiness will occur
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symptom of a serious underlying medical illness.
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before use.
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Drug Facts (continued)

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Inactive ingredients corn starch, dicalcium
phosphate, FD & C blue #1 aluminum lake, magnesium
stearate, microcrystalline cellulose, polyethylene glycol,
polyvinyl alcohol, silica gel, stearic acid, talc, titanium
dioxide

Questions or comments? 1-800-426-9391

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Simply Sleep®, 50844 REV0516E36707

8-0316-367-07-R
REV0516E36707

ITEM# 165282
Distributed by: Greenbrier International, Inc.
Chesapeake, VA 23320 USA

· Diphenhydramine HCl 25 mg
Nighttime Sleep-Aid

36 caplets

Assured 44-367

SLEEP AID NIGHTTIME

diphenhydramine hcl tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:33992-0367
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:33992-0367-7	3 in 1 CARTON	06/10/2000	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:33992-0367-2	1 in 1 CARTON	06/10/2000	
2		100 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	06/10/2000	

Labeler - GREENBRIER INTERNATIONAL, INC. (610322518)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(33992-0367)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(33992-0367)

Revised: 10/2016

GREENBRIER INTERNATIONAL, INC.