

**SLEEP AID NIGHTTIME- diphenhydramine hydrochloride 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

- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- 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

- drowsiness will occur
- avoid alcoholic drinks
- do not drive a motor vehicle or operate machinery

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.

Overdose warning: 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 28 mg
- **TAMPER EVIDENT: DON 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)
- 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

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

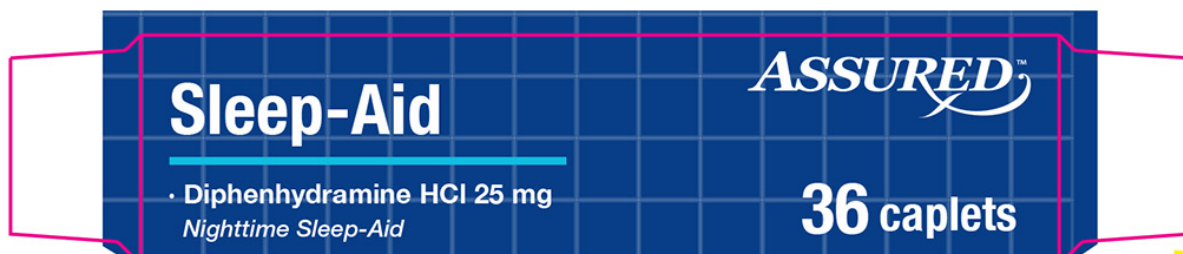
50844 REV0814C36707

ITEM# 165282

Distributed by: **Greenbrier International, Inc.**

Chesapeake, VA 23320 USA

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



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B-0316-367-07-R
REV0814C36707

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A1723R

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Drug Facts	Active ingredient (in each caplet) Diphenhydramine HCl 25 mg
Purpose	Nighttime sleep-aid
Use	for relief of occasional sleeplessness
Warnings	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> glaucoma a breathing problem such as emphysema or chronic bronchitis 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	<ul style="list-style-type: none"> do not drive a motor vehicle or operate machinery driveness will occur avoid alcoholic drinks
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.

Drug Facts (continued)

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) at once.

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LEBG251R

SLEEP AID NIGHTTIME

diphenhydramine hcl tablet, film coated

Product Information

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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (DIPHENHYDRAMINE)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS	
FD&C BLUE NO. 1	
MAGNESIUM STEARATE	
CELLULOSE, MICROCRYSTALLINE	
POLYETHYLENE GLYCOLS	
POLYVINYL ALCOHOL	
STEARIC ACID	
TALC	
TITANIUM DIOXIDE	

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		
1		12 in 1 BLISTER PACK; Combination Product Type = C112160		
2	NDC:33992-0367-2	1 in 1 CARTON		
2		100 in 1 BOTTLE; Combination Product Type = C112160		

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)

Revised: 2/2015

GREENBRIER INTERNATIONAL, INC.