NIGHTTIME SLEEP AID- diphenhydramine hydrochloride tablet, film coated Target Corporation

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.

Target 44-367

Active ingredient (in each caplet)

Diphenhydramine HCl 25 mg

Purpose

Nighttime sleep-aid

Uses

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 orIn case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical even if you do not notice any signs or symptoms.

Directions

- do not take more than directed (see Overdose warning)
- 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

- store at 25° (77°C); 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?

1-800-910-6874

Principal Display Panel

NDC 11673-367-12

nighttime sleep aid

diphendhyramine HCl, 25 mg

Compare to active ingredient in Simply Sleep®*

non habit forming

up&upTM

NIGHT

100 CAPLETS

SHOWN ACTUAL SIZE ABOVE

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

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

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Target 44-367

NIGHTTIME SLEEP AID diphenhydramine hcl tablet, film coated **Product Information** HUMAN OTC DRUG LABEL NDC:11673-367 Product Type Item Code (Source)

Route of Administration ORAL DEA Schedule

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DIPHENHYDRAMINE HYDRO CHLO RIDE (DIPHENHYDRAMINE)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg	

Inactive Ingredients			
Ingredient Name	Strength		
CALCIUM PHO SPHATE, DIBASIC, ANHYDRO US			
FD&C BLUE NO. 1			
MAGNESIUM STEARATE			
CELLULOSE, MICRO CRYSTALLINE			
POLYETHYLENE GLYCOLS			
POLYVINYL ALCOHOL			
STEARIC ACID			
TALC			
TITANIUM DIO XIDE			

Product Characteristics			
Color	BLUE	Score	no score
Shape	CAPSULE	Size	13mm
Flavor		Imprint Code	44;367
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11673-367-08	2 in 1 CARTON		
1		12 in 1 BLISTER PACK		
2	NDC:11673-367-12	1 in 1 CARTON		
2		100 in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part338	06/10/2000	

Labeler - Target Corporation (006961700)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(11673-367)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(11673-367)

Revised: 7/2013 Target Corporation