

## **NIGHTTIME SLEEP AID- diphenhydramine hcl 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.*

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### **Target 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.**

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
- 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?***

**Call 1-800-910-6874**

### **Principal Display Panel**

**Compare to** active ingredient in  
**Simply Sleep<sup>®</sup> Caplets\***

NDC 11673-367-12

#### **nighttime sleep aid**

diphenhydramine HCl, 25 mg/ sleep aid  
non-habit forming

#### **up&up<sup>®</sup>**

100 CAPLETS

ACTUAL SIZE

**100**

CAPLETS

**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<sup>®</sup> Caplets.  
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## NIGHTTIME SLEEP AID

diphenhydramine hcl tablet, film coated

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11673-367
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
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
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:11673-367-12	1 in 1 CARTON	06/10/2000	
1		100 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:11673-367-03	1 in 1 PACKAGE	06/10/2000	05/25/2018
2		10 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** - 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)