# NIGHTTIME SLEEP AID- diphenhydramine hydrochloride capsule SUPERVALU 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.

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**Equaline 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 or In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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°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?

1-877-932-7948

## **Principal Display Panel**

**equaline**®

compare to Simply Sleep® active ingredient†

NDC 41163-367-06

nighttime

# sleep aid

diphenhydramine HCl 25 mg

- wake up rested and refreshed
- safe, non-habit forming
- contains no pain relievers

200 caplets

#### **DOES NOT CONTAIN GLUTEN**

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

50844 REV0612A36706

#### DISTRIBUTED BY SUPERVALU INC.

EDEN PRARIE, MN 55344 USA

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



Equaline 44-367

## NIGHTTIME SLEEP AID

diphenhydramine hcl capsule				
Product Information				
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:41163-367	
Route of Administration	ORAL	DEA Schedule		
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	

mactive ingredients	
Ingredient Name	Strength
CALCIUM PHO SPHATE, DIBASIC, ANHYDRO US	
FD&C BLUE NO. 1	
MAGNESIUM STEARATE	
CELLULO SE, 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			

# Packaging

1	1 ackaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:41163-367-06	1 in 1 CARTON			
1		200 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 - SUPERVALU INC. (006961411)

# Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(41163-367)

# Establishment

Establishment				
Name	Address	ID/FEI	Business Operations	
LNK International, Inc.		832867894	MANUFACTURE(41163-367)	

Revised: 7/2013 SUPERVALU INC.