# SOMNAPURE CLINICAL STRENGTH- diphenhydramine hydrochloride tablet, coated NutraClick, LLC

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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### Somnapure Clinical Strength

### Drug Facts

## **Active ingredient (in each caplet)**

Diphenhydramine HCl 50 mg

### **Purpose**

Nighttime sleep aid

□*Use* □for relief of occasional sleeplessness

### **□Warnings**

### Do not use

- Din 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**

- Illa breathing problem such as emphysema or chronic bronchitis
- glaucoma
- difficulty in urination due to enlargement of the prostate gland

**Ask a doctor before use if you are** Itaking sedatives, tranquilizers, or any other sleep aid.

**When using this product**, avoid alcoholic drinks.

**Stop use and ask a doctor** Dif sleeplessness persists continuously for more than two weeks. Insomnia may be a symptom of a serious underlying medical illness.

**If pregnant or breastfeeding,** Dask a health professional before use.

**□Keep out of reach of children.** □ In case of overdose, get medical help or contact a poison control center right away.

### Directions

• adults and children 12 years of age and older: 1 caplet (50 mg) at bedtime if needed, or as directed by a doctor

## **Other information**

• store at 15°-30°C (59°-86°F)

□ *Inactive ingredients* □ collodial silicon dioxide, croscarmellose sodium, dibasic calcium phosphate dihydrate, FD&C blue no. 1 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, mineral oil, stearic acid

**Questions of comments? Call** 1-855-606-6507

### **Peak Life**

# **Somnapure® Clinical Strength**

# Nighttime Sleep Aid / Diphenhydramine HCL

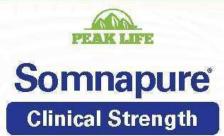
- Fall Asleep Quickly
- Wake Up Energized
- Non-Habit-Forming

# #1 Doctor-Recommended Ingredient

# 30 Sleep Caplets One Caplet per Dose

Distributed by Peak Life, LLC, a subsidiary of NutraClick, LLC PeakLife.com/1-855-606-6507 Boston, MA 02108





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30 Caplets



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### SOMNAPURE CLINICAL STRENGTH

diphenhydramine hydrochloride tablet, coated

### **Product Information**

HUMAN OTC DRUG NDC:69721-002 Product Type Item Code (Source)

ORAL Route of Administration

### **Active Ingredient/Active Moiety**

**Ingredient Name Basis of Strength** Strength DIPHENHYDRAMINE HYDRO CHLO RIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - DIPHENHYDRAMINE 50 mg UNII:8GTS82S83M) HYDROCHLORIDE

# **Inactive Ingredients Ingredient Name** Strength COLLOIDAL SILICON DIO XIDE (UNII: ETJ7Z6 XBU4) CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48) DIBASIC CALCIUM PHO SPHATE DIHYDRATE (UNII: O7TSZ97GEP) FD&C BLUE NO. 1 (UNII: H3R47K3TBD) HYPROMELLOSES (UNII: 3NXW29V3WO) MAGNESIUM STEARATE (UNII: 70097M6I30) CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U) MINERAL OIL (UNII: T5L8T28FGP) STEARIC ACID (UNII: 4ELV7Z65AP)

Product Characteristics						
Color	blue	Score	2 pieces			
Shape	OVAL	Size	14mm			
Flavor		Imprint Code	SPCS			
Contains						

Packaging					
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
1	NDC:69721-002-30	1 in 1 BOX			
1		30 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	05/26/2015				

# Labeler - NutraClick, LLC (831011809)

Establishment						
Name	Address	ID/FEI	Business Operations			
Time-Cap Labs, Inc.		037052099	manufacture(69721-002)			

Revised: 5/2015 NutraClick, LLC