

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.

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

- 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

- a 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 taking sedatives, tranquilizers, or any other sleep aid.

When using this product, avoid alcoholic drinks.

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

If pregnant or breastfeeding, 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 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 colloidal 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



Somnapure
Clinical Strength

PEAK LIFE

Trouble Sleeping?

Many of us struggle to get the quality sleep that we deserve. Somnapure Clinical Strength is the safe and effective nighttime sleep aid that contains the #1 doctor recommended ingredient for taking asleep quickly, so you can wake up feeling refreshed and energized. Let Somnapure remind you how it feels to have a full, rejuvenating night's sleep again.

Who We Are

Peak Life is a leading provider of premium specialty supplements and over 30 counter ingredients. Our R&D and research-based scientists utilize cutting edge research to provide the highest quality of products whenever possible. With Peak Life, you can rest easy knowing that you are getting the very best that science has to offer.

Questions or Comments?

Call 1-855-606-6507 or visit www.peaklife.com

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America's Sleep Aid

Somnapure Clinical Strength

The newest addition to the Somnapure family, Somnapure Clinical Strength utilizes the #1 doctor recommended ingredient for sleep.

Somnapure Natural Sleep Aid

The original Somnapure formula takes a natural approach to help you fall asleep faster, stay asleep at night, and wake up feeling refreshed.

Somnapure PM Minor Pain Management

Somnapure PM builds on our original natural sleep formula and adds a natural pain management component to help relieve minor aches and pains throughout the night.



Somnapure Clinical Strength
Nighttime Sleep Aid / Diphenhydramine HCL

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

30 Sleep Caplets One Caplet per Dose

Somnapure
Our mission is to promote healthy living through the development of innovative products using high quality ingredients.

Drug Facts	Active ingredient (in each caplet)	Purpose
<p>Use: For relief of occasional sleeplessness.</p> <p>Warnings:</p> <ul style="list-style-type: none"> Do not use if you are under 17 years of age. Do not use if you are pregnant, breastfeeding, or taking MAO inhibitors. Do not use if you are taking other sedatives. Do not use if you have a breathing problem such as emphysema or chronic bronchitis. Do not use if you are taking other sedatives, tranquilizers, or other sleep aids. <p>When using this product, avoid alcoholic drinks.</p> <p>Keep out of reach of children. If administered to children, do not use for more than 7 days unless directed by a doctor.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a poison control center right away.</p> <p>Directions:</p> <ul style="list-style-type: none"> Take one caplet 15-30 minutes before bedtime. Do not use for more than 7 days unless directed by a doctor. <p>Other information:</p> <ul style="list-style-type: none"> Contains 30 caplets. Contains 30 mg of diphenhydramine HCL per caplet. Contains 30 mg of diphenhydramine HCL per caplet. <p>Questions or comments? Call 1-855-606-6507</p>	<p>30 mg Diphenhydramine HCL</p>	<p>Sleep Aid</p>



Let us help you



Somnapure[®] Clinical Strength

Nighttime Sleep Aid / Diphenhydramine HCl

30
Caplets



Fall Asleep Quickly
Wake Up Energized
Non-Habit-Forming

Active ingredient (in each caplet)

Diphenhydramine HCl 50 mg.....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

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

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When using this product, avoid alcoholic drinks.

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If pregnant or breastfeeding, 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 right away.

Purpose

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: colloidal silicon dioxide, croscarmellose sodium, dibasic calcium phosphate dihydrate, FD&C blue no. 1 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, mineral oil, stearic acid

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Lot # and Best By:

SOMNAPURE CLINICAL STRENGTH

diphenhydramine hydrochloride tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69721-002
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
COLLOIDAL SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (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	Marketing Start Date	Marketing End Date
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