

SOMNAPURE CLINICAL STRENGTH- diphenhydramine hydrochloride tablet, coated

Force Factor Brands 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

helps to reduce difficulty in falling asleep

□ 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 or pharmacist before use if you are taking sedatives or tranquilizers.

When using this product, avoid alcoholic beverages.

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 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 (1-800-222-1222) right away.

□ Directions

- adults and children 12 years and over: take 1 caplet at bedtime if needed or as directed by a doctor
- Children under 12 years: do not use.

□ Other information

- **each caplet contains**: calcium 50 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.
- protect from moisture

Inactive ingredients croscarmellose sodium, dibasic calcium phosphate dihydrate, FD&C blue #1 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, silicon dioxide, stearic acid, talc, titanium dioxide, yellow iron oxide

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

Principal display panel

Force Factor Somnapure

Clinical Strength

Nighttime Sleep Aid / Diphenhydramine HCl

#1 Doctor-Recommended Ingredient

Fall Asleep Quickly

Wake Up Energized

Non-Habit-Forming

30 Caplets

One Caplet per Dose



Somnapure[®]

Clinical Strength

Diphenhydramine HCl / Nighttime Sleep Aid



30 CAPLETS
ONE CAPLET PER DOSE

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

Drug Facts KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

| | |
|---|---|
| <p>Active ingredient (in each caplet) Diphenhydramine HCl 50 mg.....Nighttime sleep-aid</p> <p>Use helps to reduce difficulty falling asleep</p> <p>Warnings See carton for complete warnings</p> <p>Do not use ■ in children under 12 years of age ■ with any other product containing diphenhydramine, even one used on skin</p> <p>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.</p> <p>Directions ■ adults and children 12 years and over: take 1 caplet at bedtime if needed or as directed by a doctor ■ children under 12 years: do not use</p> <p>Other information ■ each caplet contains: calcium 50 mg ■ TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING ■ protect from moisture</p> | <p>Purpose Nighttime sleep-aid</p> <p>Drug Facts (continued) ■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F) ■ use by expiration date on package</p> <p>Inactive ingredients croscarmellose sodium, dibasic calcium phosphate dihydrate, FD&C blue #1 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, silicon dioxide, stearic acid, talc, titanium dioxide, yellow iron oxide</p> <p>Questions or comments? 1-855-606-6507 ORG051668701</p> <p> Distributed by Force Factor, LLC, a subsidiary of NutraClick, LLC, Boston, MA 02210 • 1-855-606-6507 Proudly manufactured in the U.S. from foreign and domestic ingredients.</p> <p> Lot # and Exp. Date: FF9-00481-LS 19-1</p> |
|---|---|

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FACTOR**

**FORCE
FACTOR**

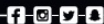
AMERICA'S SLEEP AID®

TROUBLE SLEEPING?

Many of us struggle to get the quality sleep we deserve. Somnapure® Clinical Strength is the safe and effective nighttime sleep aid that contains the #1 doctor-recommended ingredient for falling asleep quickly, so you can wake up feeling refreshed and energized.



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Printed and manufactured in the U.S. from foreign and domestic ingredients.



**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 contains key natural ingredients to help you fall asleep faster, stay asleep longer, and wake up feeling refreshed.

**Somnapure®
Clinical Strength**

Diphenhydramine HCl / Nighttime Sleep Aid

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



30 CAPLETS
ONE CAPLET PER DOSE

**NEW LOOK
SAME GREAT PRODUCT**

Lot # and Best By:



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

Drug Facts KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Active ingredient (in each caplet) Diphenhydramine HCl 50 mg. **Purpose** Nighttime sleep-aid

Use helps to reduce difficulty falling asleep

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
 - difficulty in urination due to enlargement of the prostate gland
 - glaucoma
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- When using this product, avoid alcoholic beverages.
- 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.
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Questions or comments? 1-855-606-6307

B-0730-687-01-N
ORG051668701

SOMNAPURE CLINICAL STRENGTH

diphenhydramine hydrochloride tablet, coated

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:69721-005 |
| 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 |
|---|----------|
| CROSCARMELOSE SODIUM (UNII: M28OL1HH48) | |
| DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP) | |
| FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| TALC (UNII: 7SEV7J4R1U) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| FERRIC OXIDE YELLOW (UNII: EX438O2MRT) | |

Product Characteristics

| | | | |
|-----------------|------|---------------------|----------|
| Color | blue | Score | no score |
| Shape | OVAL | Size | 15mm |
| Flavor | | Imprint Code | 44687 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:69721-005-30 | 1 in 1 CARTON | 03/20/2018 | |
| 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 | 03/20/2018 | |

Labeler - Force Factor Brands LLC (831011809)

Revised: 1/2022

Force Factor Brands LLC