

SOMINEX MAX- diphenhydramine hcl tablet
Medtech Products 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.

Sominex Max

Drug Facts

Active ingredient

(in each caplet)

Diphenhydramine HCl 50 mg

Purpose

Nighttime sleep-aid

Use

helps 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
- with other antihistamines

Ask a doctor before use if you have

- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- 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

- avoid alcoholic beverages
- be careful when driving a motor vehicle or operating machinery
- drowsiness will occur

Stop use and ask a doctor if

sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of 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

- **adults and children 12 years and older:** take 1 caplet at bedtime if needed, or as directed by your doctor

Other information

store at room temperature 20°- 25°C (68°-77°F)

Inactive ingredients

croscarmellose sodium, dicalcium phosphate, FD&C blue no. 1 lake, hypromellose, lactose, magnesium stearate, microcrystalline cellulose, mineral oil, silica, stearate acid, talc, titanium dioxide, triacetin

Questions?

1-866-255-5202

PRINCIPAL DISPLAY PANEL

MAXIMUM STRENGTH FORMULA

Sominex®

NIGHTTIME SLEEP-AID DIPHENHYDRAMINE HCl

16 TABLETS

Drug Facts

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

Use helps 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 - with other antihistamines

Ask a doctor before use if you have - a breathing problem such as emphysema or chronic bronchitis - glaucoma - 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 - avoid alcoholic beverages - be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of serious underlying medical illness.

If pregnant or breast-feeding, ask a health professional before use.

Drug Facts (continued)

Keep out of reach of children. Overdose warning: In case of accidental overdose get medical help or contact a Poison Control Center right away.

Directions
-adults and children 12 years and older: take 1 caplet at bedtime if needed or as directed by your doctor.

Other information
- each caplet contains: calcium 50 mg
- store below 25°C (77°F)

Inactive ingredients
carnauba wax, crospovidone, dibasic calcium phosphate, FD&C blue #1 aluminum lake, hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, silicon dioxide, starch, titanium dioxide

Questions or comments?
1-866-255-5202 (English/Spanish)

MAXIMUM STRENGTH

Sominex®

Tamper Evident Feature:
This product is protected in a sealed blister. Do not use if blister or printed foil is broken.



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Tarrytown, NY 10591
A Prestige Brands Company
Made in USA
SX005101

EXP. DATE/LOT NO.

16 CAPLETS

Helps You Fall Asleep Fast

One Caplet

CONTAINS THE #1 DOCTOR-RECOMMENDED SLEEP-AID INGREDIENT

NIGHTTIME SLEEP-AID • DIPHENHYDRAMINE HCl

Sominex®

MAXIMUM STRENGTH

Safe, Effective & Non-Habit Forming

NIGHTTIME SLEEP-AID • DIPHENHYDRAMINE HCl

Sominex®

MAXIMUM STRENGTH

WAKE RESTED & REFRESHED

MAXIMUM STRENGTH

SOMINEX MAX

diphenhydramine hcl tablet

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:63029-505

| | |
|--------------------------------|------|
| 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) | |
| CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP) | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |
| LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| MINERAL OIL (UNII: T5L8T28FGP) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| TALC (UNII: 7SEV7J4R1U) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| TRIACETIN (UNII: XHX3C3X673) | |

Product Characteristics

| | | | |
|-----------------|-------------------|---------------------|----------|
| Color | BLUE (light blue) | Score | no score |
| Shape | CAPSULE | Size | 15mm |
| Flavor | | Imprint Code | S |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:63029-505-16 | 1 in 1 BOX | 06/01/2012 | |
| 1 | | 16 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 2 | NDC:63029-505-01 | 1 in 1 BOX | 06/01/2012 | 02/01/2019 |
| 2 | NDC:63029-505-07 | 16 in 1 BLISTER PACK; 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 | 06/01/2012 | |

