

**SOMINEX MAX- diphenhydramine hcl tablet**  
**Medtech Products Inc.**

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**Sominex Max**

***Drug Facts***

***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
- 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)
- keep carton for future reference

***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



## SOMINEX MAX

diphenhydramine hcl tablet

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:63029-505 |
| <b>Route of Administration</b> | ORAL           |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength                | Strength |
|--|----------------------------------|----------|
| <b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40)<br>(DIPHENHYDRAMINE - UNII:8GTS82S83M) | DIPHENHYDRAMINE<br>HYDROCHLORIDE | 50 mg    |

### Inactive Ingredients

| Ingredient Name | Strength |
|-----------------|----------|
|-----------------|----------|

|   |
|---|
| <b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)                  |
| <b>CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE</b> (UNII: O7TSZ97GEP) |
| <b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)                   |
| <b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)             |
| <b>LACTOSE, UNSPECIFIED FORM</b> (UNII: J2B2A4N98G)             |
| <b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)                    |
| <b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)           |
| <b>MINERAL OIL</b> (UNII: T5L8T28FGP)                           |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)                       |
| <b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)                          |
| <b>TALC</b> (UNII: 7SEV7J4R1U)                                  |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)                      |
| <b>TRIACETIN</b> (UNII: XHX3C3X673)                             |

### Product Characteristics

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

### Packaging

| # | Item Code        | Package Description                                     | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:63029-505-01 | 1 in 1 BOX  | 06/01/2012           | 02/01/2019         |
| 1 | NDC:63029-505-07 | 16 in 1 BLISTER PACK; Type 0: Not a Combination Product |                      |                    |
| 2 | NDC:63029-505-16 | 1 in 1 BOX  | 06/01/2012           |                    |
| 2 |                  | 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 Drug | M010                                     | 06/01/2012           |                    |

**Labeler** - Medtech Products Inc. (122715688)