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 difficultly 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 **o**verdose**,** 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 20º- 25ºC (68º-77ºF)

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			
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
CROSCARMELLOSE 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	

Labeler - Medtech Products Inc. (122715688)