SOMINEX- diphenhydramine hydrochloride tablet, film coated
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-Original

Drug Facts

Active Ingredient

(in each tablet)

Diphenhydramine HCl 25 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

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 accidental overdose get medical help or contact a Poison Control Center right away.

Directions

Adults and children 12 years and older: take 2 tablets at bedtime if needed, or as directed by your doctor

Other information

- each tablet contains: **calcium 10 mg**
- store at 20º- 25ºC (68º-77ºF)

Inactive ingredients

cellulose, microcrystalline, croscarmellose sodium, FD&C blue no. 1, hypromellose, lactose monohydrate, light mineral oil, magnesium stearate, silicon dioxide, stearic acid, talc, titanium dioxide, triacetin

Questions?

1-866-255-5202 weekdays or visit www.sominex.com

CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP)

PRINCIPAL DISPLAY PANEL

ORIGINAL FORMULA

Sominex®

NIGHTTIME SLEEP-AID DIPHENHYDRAMINE HCl

16 TABLETS

PRINCIPAL DISPLAY PANEL

ORIGINAL FORMULA

Sominex®

NIGHTTIME SLEEP-AID DIPHENHYDRAMINE HCl

32 TABLETS

PRINCIPAL DISPLAY PANEL

ORIGINAL FORMULA

Sominex®

NIGHTTIME SLEEP-AID DIPHENHYDRAMINE HCl

72 TABLETS

SOMINEX

diphenhydramine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63029-554
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
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	ROUND	**Size**	10mm
Flavor		**Imprint Code**	S;S
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63029-554-32	4 in 1 BOX	06/01/2012	
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:63029-554-16	2 in 1 BOX	06/01/2012	
2		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:63029-554-01	9 in 1 BOX	06/01/2012	
3		8 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)

Revised: 5/2020 Medtech Products Inc.