NIGHTTIME SLEEP AID MAXIMUM STRENGTH- diphenhydramine hcl tablet, film coated
Walgreen Company

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.

Walgreens 44-687

Active ingredient (in each caplet)

Diphenhydramine HCl 50 mg

Purpose

Nighttime sleep-aid

Uses

- for occasional sleeplessness
- reduces time to fall asleep if you have difficulty falling asleep

Warnings

Do not use

- for 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 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 right away.

Directions

- **do not take more than directed**

- 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
- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- protect from moisture
- store at 25ºC (77ºF); excursions permitted between 15º-30ºC (59º-86ºF)
- see end flap for expiration date and lot number

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 or comments?

1-800-426-9391

Principal Display Panel

Compare to Maximum
Strength Sominex®
active ingredient††

NDC 0363-0687-21

Walgreens

Nighttime Sleep Aid
DIPHENHYDRAMINE HCl 50 mg / NIGHTTIME SLEEP AID

NIGHTTIME MAXIMUM STRENGTH CAPLETS

16 CAPLETS

Actual Size

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

††This product is not manufactured or distributed by Medtech Products Inc., owner of the registered trademark Maximum Strength Sominex®.

50844 REV1019A68721

Walgreens Pharmacist Recommended.
Walgreens Pharmacist Survey

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Walgreens 44-687

NIGHTTIME SLEEP AID MAXIMUM STRENGTH

diphenhydramine hcl tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0363-0687
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)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	

Product Characteristics			
Color	BLUE	**Score**	no score
Shape	OVAL	**Size**	15mm
Flavor		**Imprint Code**	44;687
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0363-0687-21	4 in 1 CARTON	07/31/2016	
1		4 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	07/31/2016	

Labeler - Walgreen Company (008965063)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(0363-0687)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(0363-0687)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(0363-0687)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(0363-0687)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(0363-0687)

Revised: 4/2020 Walgreen Company