

SLEEP TABS- diphenhydramine hcl tablet

Major Pharmaceuticals

Major 44-189

Active ingredient (in each tablet)

Diphenhydramine HCl 25 mg

Purpose

Nighttime sleep-aid

Uses

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

Warnings

Do not use

- with any other product containing diphenhydramine, even one used on skin
- for children under 12 years of age

Ask a doctor before use if you have

- a breathing problem such as emphysema or chronic bronchitis
- difficulty in urination due to enlargement of the prostate gland
- glaucoma

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 2 tablets at bedtime if needed or as directed by a doctor
- children under 12 years: do not use

Other information

- **each tablet contains:** calcium 60 mg
- protect from moisture
- store at 25°C (77°F); excursions permitted between 15°C-30°C (59°F-86°F)
- 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, silicon dioxide, stearic acid

Questions or comments?

(800) 616-2471

Principal Display Panel

MAJOR®

NDC 0904-4274-51

Compare to the active
ingredient in Original
Formula Sominex®*

Sleep Tabs

Diphenhydramine HCl

25 mg

Nighttime Sleep-Aid

Actual Size

50 Tablets

**TAMPER EVIDENT: DO NOT USE IF
IMPRINTED SAFETY SEAL UNDER CAP
IS BROKEN OR MISSING**

*This product is not manufactured or distributed by Medtech
Products Inc., owner of the registered trademark Original
Formula Sominex®. 50844 REV1019N18915

Distributed by:

MAJOR® PHARMACEUTICALS

Rev. 01/20 M-17 Re-order No. 700607



diphenhydramine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-4274	
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	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)				
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
Product Characteristics				
Color	blue	Score	no score	
Shape	ROUND	Size	10mm	
Flavor		Imprint Code	44;189	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-4274-51	1 in 1 CARTON	04/10/1990	
1		50 in 1 BOTTLE, PLASTIC; 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		04/10/1990	

Labeler - Major Pharmaceuticals (191427277)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(0904-4274)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(0904-4274) , pack(0904-4274)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(0904-4274)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(0904-4274)

Revised: 3/2024

Major Pharmaceuticals