# DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine hydrochloride tablet AAA Pharmaceutical, 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.

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#### **Diphenhydramine HCl Tablets**

**Drug Facts** 

#### Active ingredient (in each tablet)

Diphenhydramine HCl 25 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

#### Ask a doctor before use if you have

- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- 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 drinks

**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 right away.

#### **Directions**

adults and children 12 years of age and over: take 2 tablets at bedtime if needed, or as directed by a
doctor

#### Other information

- each tablet contains: calcium 85 mg
- store at room temperature 15°-30°C (59°-86°F)

• retain carton for complete product information

# **Inactive ingredients**

colloidal silicon dioxide, croscarmellose sodium, dibasic calcium phosphate, FD&C blue #1, magnesium stearate, microcrystalline cellulose

Distributed by: AAA Pharmaceutical, Inc. 681 Main Street Lumberton, NJ 08048

### PRINCIPAL DISPLAY PANEL - 16 Tablet Blister Pack Carton

RESTORE u

NDC 57344-019-01 †COMPARE TO THE ACTIVE INGREDIENT IN SOMINEX®

Get To Sleep Safely, Wake Up Refreshed

**Somnitabs NIGHTTIME SLEEP-AID**Diphenhydramine HCl **16** TABLETS - 25 mg each

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NDC 57344-019-01 †COMPARE TO THE ACTIVE

Get To Sleep Safely, Wake Up Refreshed

# Somnitab

NIGHTTIME SLEEP-AID Diphenhydramine HCI

16 TABLETS - 25 mg each

Distributed by: AAA Pharmaceutical, Inc. 681 Main Street Lumberton, NJ 08048

F101901RES\_R0

ARE TORN OR BROKEN DO NOT USE IF BLISTER UNITS

distributor of Sominex® or distributed by GlaxoSmithKline, † This product is not manufactured



#### DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride tablet

#### **Product Information**

HUMAN OTC DRUG LABEL NDC:57344-019 Product Type Item Code (Source)

**Route of Administration** 

ORAL

**DEA Schedule** 

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
<b>DIPHENHYDRAMINE HYDRO CHLO RIDE</b> (DIPHENHYDRAMINE)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg		

Inactive Ingredients				
Ingredient Name	Strength			
SILICON DIO XIDE				
CROSCARMELLOSE SODIUM				
CALCIUM PHO SPHATE, DIBASIC, ANHYDRO US				
FD&C BLUE NO. 1				
MAGNESIUM STEARATE				
CELLULOSE, MICRO CRYSTALLINE				

Product Characteristics			
Color	BLUE	Score	no score
Shape	ROUND	Size	10 mm
Flavor		Imprint Code	93XF;57344
Contains			

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:57344-019-01	2 in 1 CARTON			
1	8 in 1 BLISTER PACK			
2 NDC:57344-019-02	4 in 1 CARTON			
2	8 in 1 BLISTER PACK			
3 NDC:57344-019-03	9 in 1 CARTON			
3	8 in 1 BLISTER PACK			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL	part338	12/15/20 12		

# **Labeler** - AAA Pharmaceutical, Inc. (181192162)

Establishment			
Name	Address	ID/FEI	Business Operations
AAA Pharmaceutical, Inc.		18 119 216 2	MANUFACTURE(57344-019)

Establishment			
Name	Address	ID/FEI	Business Operations

		-
AAA Pharmaceutical, Inc.	010411533	PACK(57344-019)

Revised: 12/2012 AAA Pharmaceutical, Inc.