

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.

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®

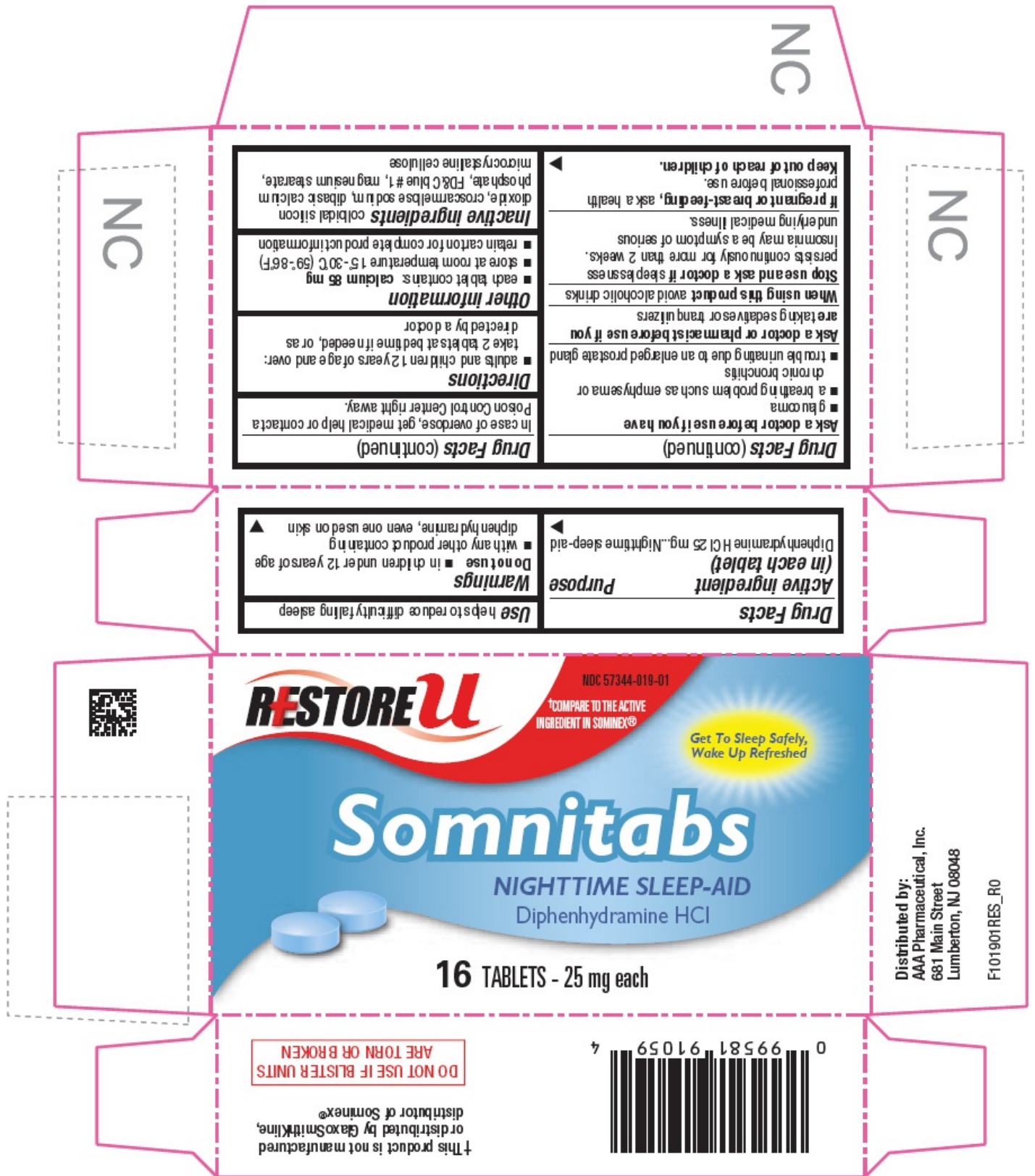
***Get To Sleep Safely,
Wake Up Refreshed***

Somnitabs

NIGHTTIME SLEEP-AID

Diphenhydramine HCl

16 TABLETS - 25 mg each



DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57344-0 19
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

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	12/15/2012	

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

Name	Address	ID/FEI	Business Operations
AAA Pharmaceutical, Inc.		181192162	MANUFACTURE(57344-019)

Establishment

Name	Address	ID/FEI	Business Operations
AAA Pharmaceutical, Inc.		010411533	PACK(57344-019)

Revised: 12/2012

AAA Pharmaceutical, Inc.