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 caplet)

Diphenhydramine HCl 25 mg

Purpose

Nighttime sleep-aid

Use

relieves occasional sleeplessness

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 two caplets (50 mg) at bedtime if needed, or as directed by a doctor

Other information

- each caplet 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, magnesium stearate, microcrystalline cellulose

Distributed by:

AAA Pharmaceutical, Inc. 681 Main Street Lumberton, NJ 08048

PRINCIPAL DISPLAY PANEL - 72 Caplet Bottle Carton

RESTORE u

NDC 57344-028-03

†COMPARE TO THE ACTIVE INGREDIENT IN NYTOL® QUICK CAPS

Safe & Effective Fall Asleep Fast

Nyt-time Sleep Caps

NIGHTTIME SLEEP-AID

Diphenhydramine HCl

72 CAPLETS - 25 mg each

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Purpose sleep-aid

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Drug Facts



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Nyt-time Sleep Caps

NIGHTTIME SLEEP-AID
Diphenhydramine HCI

72 CAPLETS - 25 mg each

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Drug Facts (continued)

DIPHENHYDRAMINE HYDROCHLORIDE

This product is not manufactured or distributed by GlaxoSmithKline, distributor of Nytor® QuickCapes

diphenhydramine hydrochloride tablet

Product Information

Product TypeHUMAN OTC DRUG LABELItem Code (Source)NDC:57344-028

Route of Administration ORAL DEA Schedule

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

Inactive Ingredients			
Ingredient Name	Strength		
SILICON DIO XIDE			
CROSCARMELLOSE SODIUM			
CALCIUM PHO SPHATE, DIBASIC, ANHYDRO US			
MAGNESIUM STEARATE			
CELLULO SE, MICRO CRYSTALLINE			

Product Characteristics			
Color	WHITE	Score	no score
Shape	OVAL	Size	15mm
Flavor		Imprint Code	93;XF;57344
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57344-028-01	2 in 1 CARTON		
1		8 in 1 BLISTER PACK		
2	NDC:57344-028-02	4 in 1 CARTON		
2		8 in 1 BLISTER PACK		
3	NDC:57344-028-03	1 in 1 CARTON		
3		72 in 1 BOTTLE, PLASTIC		
4	NDC:57344-028-04	24 in 1 BOTTLE, PLASTIC		
5	NDC:57344-028-05	72 in 1 BOTTLE, PLASTIC		

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(57344-028)

Establishment			
Name	Address	ID/FEI	Business Operations

AAA Pharmaceutical, Inc. 010411533 PACK(57344-028)

Revised: 12/2012 AAA Pharmaceutical, Inc.