

**DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine hydrochloride tablet, coated**

**AAA Pharmaceutical, Inc.**

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**RES - 1091 - 2019-1014**

***Drug Facts***

**Active ingredient (in each caplet)**

Diphenhydramine HCl 25 mg

**Purpose**

Nighttime sleep-aid

**Use**

for relief of occasional sleeplessness

**Warnings**

**Do not use**

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

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

- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland
- glaucoma

**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**

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adults and	take 2 caplets at bedtime
children 12 years	if needed, or as directed

of age and over	by a doctor
children under 12 years of age	do not use

### **Other information**

- each caplet contains: **calcium 45 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, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, titanium dioxide

### **Distributed by:**

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

### **PRINCIPAL DISPLAY PANEL - 24 Caplet Carton**

RESTORE U

NDC 57344-091-03

†COMPARE TO THE ACTIVE INGREDIENT IN SIMPLY SLEEP®

Rest Simply

actual size

Diphehydramine HCl

Nighttime Sleep-Aid

Helps You Fall Asleep Fast, Non-Habit Forming, Use as Directed

100 CAPLETS - 25 MG EACH



## DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride tablet, coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:57344-091
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS</b> (UNII: L11K75P92J)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	blue	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	11mm
<b>Flavor</b>		<b>Imprint Code</b>	25;052
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57344-091-03	1 in 1 CARTON	10/05/2018	
1		100 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	10/05/2018	

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