DIPHENHYDRAMINE- diphenhydramine hydrochloride capsule
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 Capsules

Drug Facts

Active ingredient (in each capsule)

Diphenhydramine HCl 25 mg

Purpose

Antihistamine

Uses

- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
  - runny nose
  - sneezing
  - itchy, watery eyes
  - itching of the nose or throat
- temporarily relieves these symptoms due to the common cold:
  - runny nose
  - sneezing

Warnings

Do not use with any other product containing diphenhydramine, even one used on skin

Ask a doctor before use if you have

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

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers

When using this product

- marked drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- excitability may occur, especially in children
- be careful when driving a motor vehicle or operating machinery

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

- take every 4 to 6 hours
- do not exceed 6 doses in 24 hours

adults and children 12 years of age and over	25 mg to 50 mg (1 to 2 capsules)
children 6 to under 12 years of age	12.5 mg* to 25 mg (1 capsule)
children under 6 years of age	ask a doctor

* 12.5 mg dosage strength is not available in this package. Do not attempt to break capsules.

Other information

- store at room temperature 15°-30°C (59°-86°F)
- protect from moisture
- retain carton for complete product information

Inactive ingredients

benzyl alcohol, butylparaben, D&C red #28, edible black ink, FD&C blue #1, FD&C red #40, gelatin, lactose, magnesium stearate, methylparaben, polysorbate 80, propylparaben, sodium lauryl sulfate

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

PRINCIPAL DISPLAY PANEL - 24 Capsule Blister Pack Carton

RESTORE u

NDC 57344-113-01

†COMPARE TO THE ACTIVE
INGREDIENT IN BENADRYL®
ALLERGY KAPSEALS®

Allergy Relief

Antihistamine
Diphenhydramine HCl

Relieves: • Sneezing • Runny Nose
• Itchy, Watery Eyes • Itchy Throat

24 CAPSULES

RESTORE U

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Allergy Relief

Antihistamine

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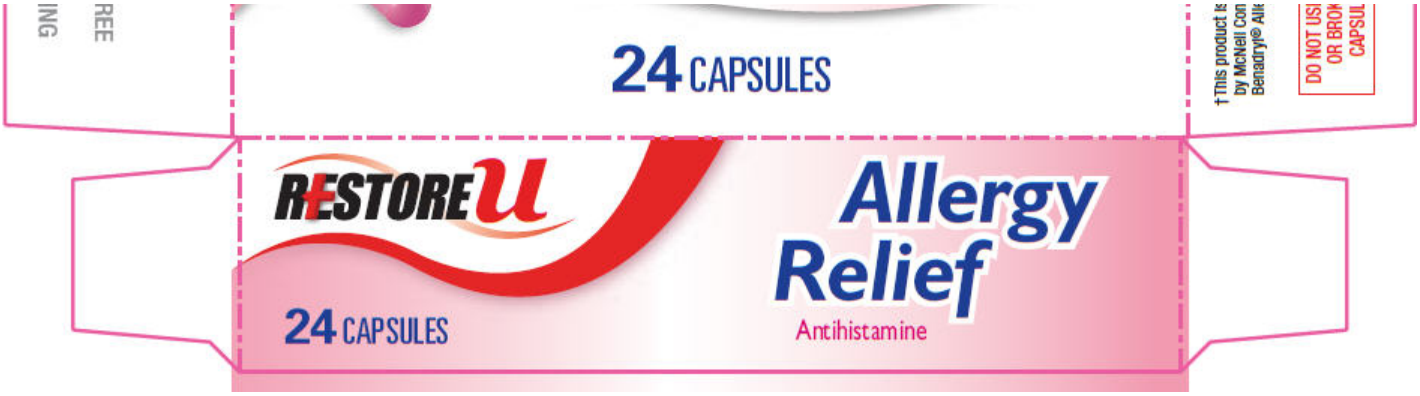

DIPHENHYDRAMINE

diphenhydramine hydrochloride capsule

Product Information

Product Type	HUMAN OTC DRUG LABEL	**Item Code (Source)**	NDC:57344-113
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (DIPHENHYDRAMINE)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL	
BUTYLPARABEN	
D&C RED NO. 28	
FD&C BLUE NO. 1	
FD&C RED NO. 40	
GELATIN	
LACTOSE	
MAGNESIUM STEARATE	
METHYLPARABEN	
POLYSORBATE 80	
PROPYLPARABEN	
SODIUM LAURYL SULFATE	

Product Characteristics

Color	PINK, WHITE	**Score**	no score
Shape	OVAL	**Size**	14mm
Flavor		**Imprint Code**	A;20
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57344-113-01	2 in 1 CARTON		
1		12 in 1 BLISTER PACK		
2	NDC:57344-113-02	4 in 1 CARTON		
2		12 in 1 BLISTER PACK		
3	NDC:57344-113-03	1 in 1 CARTON		
3		100 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	12/22/2012	

Labeler - AAA Pharmaceutical, Inc. (181192162)

Revised: 1/2013 AAA Pharmaceutical, Inc.