

**DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine hydrochloride capsule**  
**Contract Pharmacy Services-PA**

*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 Hydrochloride Capsules**

**DRUG FACTS**

**ACTIVE INGREDIENT (IN EACH CAPSULE)**

Diphenhydramine Hydrochloride 25 mg

**PURPOSE**

Antihistamine

**USES**

Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies and common cold, sneezing, runny nose, itchy, watery eyes, itchy throat and nose.

**WARNINGS**

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 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 tranquilizers or sedative.

**When using this product**

you may get drowsy; avoid alcoholic drinks. Alcohol, sedatives and tranquilizers may increase drowsiness. Be careful when driving a motor vehicle or operating machinery. Excitability may occur, especially in children. Do not use any other products containing diphenhydramine.

**If pregnant or breast-feeding,**

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. (1-800-222-1222)

**DIRECTIONS**

Adults and children 12 years and over: take 25 to 50 mg (1 to 2 capsule) every 4 to 6 hours; not more than 12 capsules in 24 hours.

Children 6 years to 12 years of age: take 25 mg (1 capsule) every 4 to 6 hours; not more than 6 capsules in 24 hours.

Children under 6 years of age: ask a doctor

## **OTHER INFORMATION**

Store at controlled room temperature 59-86 degrees F.

## **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.

## **QUESTIONS OR COMMENTS?**

Distributed by:

Qualitest Pharmaceuticals, Inc.

130 Vintage Drive

Huntsville, AL 35811

Repackaged by:

Contract Pharmacy Services-PA

125 Titus Ave Suite 200

Warrington, PA 18976 USA

Original--08/2010--NJW

## **Package Label**

**DIPHENHYDRAMINE**

25 MG CAP #30



41900090100105

LOT# 10C147  
D: AP 20  
EXP: 08/11

QUALITEST

USUAL DOSAGE:  
SEE INSERT

STORAGE  
CONDITIONS: SEE  
INSERT  
(STORE AT  
CONTROLLED ROOM  
TEMPERATURE)

FILLED BY \_\_\_\_\_

CHECKED BY \_\_\_\_\_

Packaged By: Contract Pharmacy Services-PA  
125 Titus Avenue, Suite #200, Warrington, PA 18976

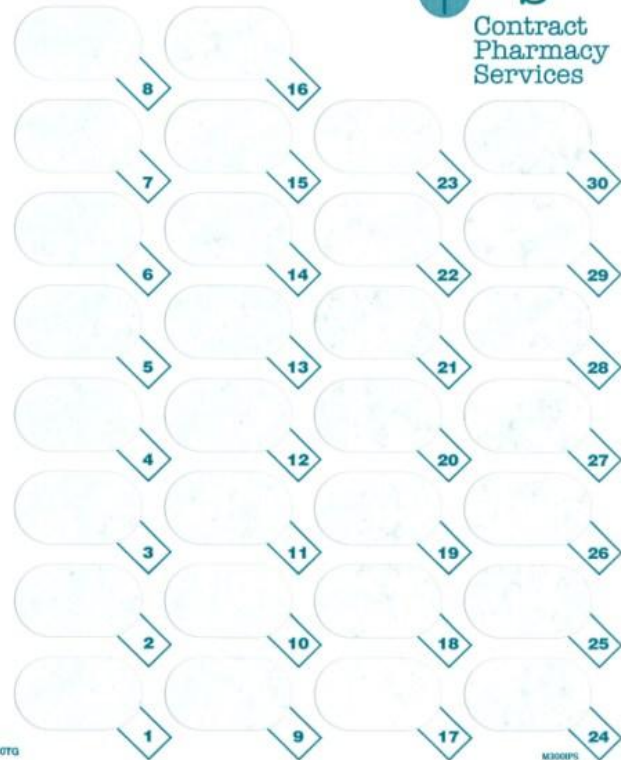
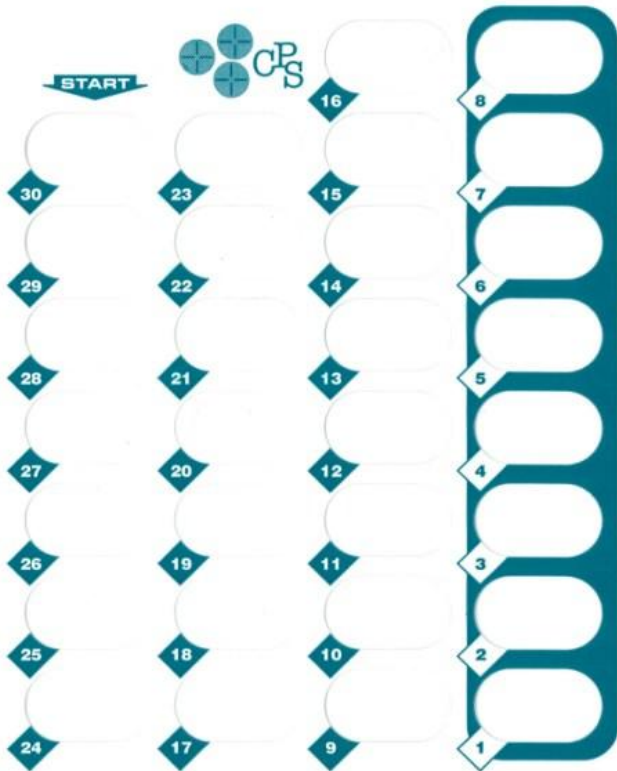
MED. \_\_\_\_\_

STRENGTH \_\_\_\_\_

EXP. DATE \_\_\_\_\_

MFG. \_\_\_\_\_

LOT NO. \_\_\_\_\_



CAUTION: This package NOT CHILD RESISTANT. Store this and all medications out of reach of children.

25 mg Capsules

**DIPHENHYDRAMINE HYDROCHLORIDE**

diphenhydramine hydrochloride capsule

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:67046-124(NDC:0603-3339)
<b>Route of Administration</b>	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
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BUTYL PARABEN (UNII: 3QP1IU3FV8)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	

<b>FD&amp;C BLUE NO. 1</b> (UNII: HBR47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>LACTOSE</b> (UNII: J2B2A4N98G)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>METHYL PARABEN</b> (UNII: A2I8C7HI9T)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>PROPYL PARABEN</b> (UNII: Z8IX2SC1OH)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	

### Product Characteristics

<b>Color</b>	PINK	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	4mm
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67046-124-30	30 in 1 BLISTER PACK		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/30/2010	

**Labeler** - Contract Pharmacy Services-PA (945429777)