

**DIPHENHYDRAMINE- diphenhydramine capsule**  
**Rebel Distributors Corp**

*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 Drug Facts**

**Active ingredient**

Diphenhydramine HCl 25mg

Diphenhydramine HCl 50mg

**Purpose**

Antihistamine

**Keep Out of Reach of Children**

**Uses**

Temporarily relieves: ° hay fever or other upper respiratory allergies like: ° runny nose  
° sneezing ° watery eyes ° itchy nose or throat

**Warnings**

**Do not use** with any other product containing Diphenhydramine HCl, including one applied topically.

**Ask a doctor or pharmacist before use** if you have ° trouble urinating due to enlarged prostate gland  
° a breathing problem such as emphysema or chronic bronchitis ° glaucoma ° if you are taking sedatives or tranquilizers

**When using this product** ° avoid alcoholic drinks ° marked drowsiness may occur ° excitability may occur, especially in children ° alcohol, sedatives & tranquilizers may increase drowsiness ° be careful when driving a motor vehicle or operating machinery.

**If pregnant or breast-feeding,** ask a health professional before use.

**In case of overdose,** get medical help or contact a Poison Control Center right away.

**Directions**

° take every 4-6 hours

° do not take more than 6 doses in 24 hours.

Adults & children 12 years & over: 1-2 capsules

Children 6 to under 12 years: 1 capsule

Children under 6: ask a doctor

**Other Information**

Store at room temperature 15°-30°C (59°-86°F)

Protect from excessive moisture

## Inactive ingredients

Lactose Monohydrate, Silicon Dioxide, Magnesium Stearate, Black Iron Oxide, Gelatin, Sodium Lauryl Sulfate, D&C Red No. 28, FD&C Red No. 40, FD&C Blue No. 1.

Distributed by:

SDA Laboratories, Inc.

Greenwich, CT 06830

Repackaged by:

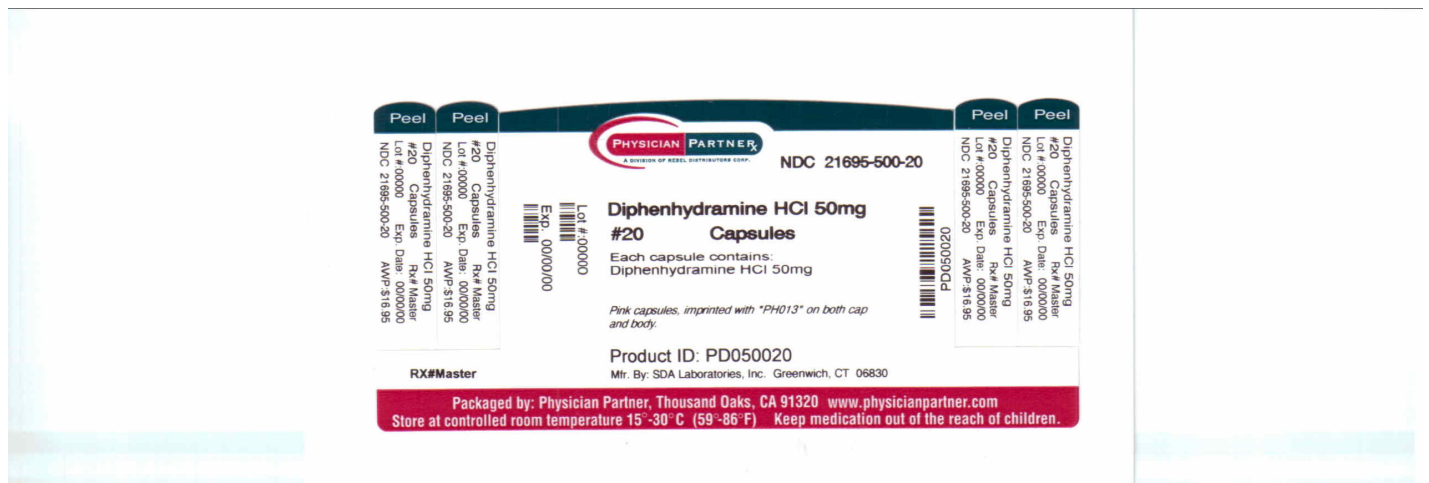
Rebel Distributors Corp

Thousand Oaks, CA 91320

## Package/Label Principal Display Panel



## Package/Label Principal Display Panel



## DIPHENHYDRAMINE

diphenhydramine capsule

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:21695-304(NDC:66424-020)
<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
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

### Product Characteristics

<b>Color</b>	PINK (Pink/White)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	15mm
<b>Flavor</b>		<b>Imprint Code</b>	PH;014
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21695-304-15	15 in 1 BOTTLE		
2	NDC:21695-304-20	20 in 1 BOTTLE		
3	NDC:21695-304-24	24 in 1 BOTTLE		
4	NDC:21695-304-30	30 in 1 BOTTLE		
5	NDC:21695-304-90	90 in 1 BOTTLE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/01/2007	

## DIPHENHYDRAMINE

diphenhydramine capsule

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:21695-500(NDC:66424-021)
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

**Product Characteristics**

<b>Color</b>	PINK	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	15mm
<b>Flavor</b>		<b>Imprint Code</b>	PH;013
<b>Contains</b>			

**Packaging**

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:21695-500-15	15 in 1 BOTTLE		
2	NDC:21695-500-20	20 in 1 BOTTLE		
3	NDC:21695-500-30	30 in 1 BOTTLE		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part348	01/01/2007	

**Labeler** - Rebel Distributors Corp (118802834)**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
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