

**DIPHENHYDRAMINE HCL - diphenhydramine hcl capsule**  
**SDA Laboratories, 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.*

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**Drug Facts**

**Active ingredient(in each capsule)**

Diphenhydramine HCL 50 mg

**Purpose**

Antihistamine

**Uses:**

- Temporarily relieves these symptoms associated with the common cold, hay fever, or other respiratory allergies.
- Sneezing.
- Nasal congestion.
- Runny nose.
- Itchy, watery eyes.

**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 and 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.

## Keep out of reach of children

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

### Directions:

- Take every 4-6 hours
- Do not take more than 6 doses in 24 hours.

Adults and children 12 years or over	1 capsule
Children under 12 years	ask a doctor

\*\*25 mg strength is not available in this package. Do not attempt to break capsules.

### Other information:

- Store at room temperature 15-30 degrees C (59-86 degrees F)
- Protect from excessive moisture

**Inactive ingredients: Black Iron Oxide, D & C Red #28, FD & C Blue #1, FD & C Red #40, Gelatin, Lactose Monohydrate, Magnesium Stearate, Silicon Dioxide, Sodium Lauryl Sulfate**

### Questions? Adverse drug event call:

1-800-687-0176

NDC 66424-021-10  
\*Compare to active ingredient in BENADRYL® Allergy

# Diphenhydramine HCl Capsules, USP

## 50 mg

TAMPER-EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS MISSING OR DAMAGED

### ANTIHISTAMINE

## 1000 CAPSULES

Not for house holds with young children

# SDA Laboratories, Inc.

<b>Drug Facts</b>	<b>Purpose</b>
<b>Active ingredient</b> (in each capsule) Diphenhydramine HCl 50 mg	Antihistamine
<b>Uses:</b> temporarily relieves these symptoms associated with the common cold, hay fever, or other respiratory allergies ■ sneezing ■ nasal congestion ■ runny nose ■ itchy, watery eyes	
<b>Warnings: Do not use</b> ■ with any other product containing Diphenhydramine HCl, including one applied topically. <b>Ask a doctor or pharmacist before use</b> 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	
<b>When using this product</b> ■ 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	
<b>If pregnant or breast-feeding</b> , ask a health professional before use. <b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away.	
<b>Directions:</b> ■ take every 4-6 hours ■ do not take more than 6 doses in 24 hours Adults & children 12 years & over 1 capsule Children under 12 years ask a doctor	
**25 mg strength is not available in this package. Do not attempt to break capsules.	
<b>Other information:</b> ■ store at room temperature 15°-30°C (59°-86°F) ■ protect from excessive moisture	
<b>Inactive ingredients:</b> Black Iron Oxide, D & C Red#28, FD & C Blue#1, FD & C Red#40, Gelatin, Lactose Monohydrate, Magnesium Stearate, Silicon Dioxide, Sodium Lauryl Sulfate	
<b>Questions? Adverse drug event call:</b> 1-800-687-0176	

\*SDA Laboratories, Inc., Greenwich, CT 06830 is not affiliated with the owner of the trademark BENADRYL® Allergy.  
MADE IN USA  
L, Rev. 05/11



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## DIPHENHYDRAMINE HCL

diphenhydramine hcl capsule

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:66424-021	
<b>Route of Administration</b>	ORAL			
<b>Active Ingredient/Active Moiety</b>				
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>	
	DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	50 mg	
<b>Inactive Ingredients</b>				
	<b>Ingredient Name</b>		<b>Strength</b>	
	FERROSO FERRIC OXIDE (UNII: XM0M87F357)			
	D&C RED NO. 28 (UNII: 767IP0Y5NH)			
	FD&C BLUE NO. 1 (UNII: HBR47K3TBD)			
	FD&C RED NO. 40 (UNII: WZB9127XOA)			
	GELATIN (UNII: 2G86QN327L)			
	LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)			
	MAGNESIUM STEARATE (UNII: 70097M6I30)			
	SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
	SODIUM LAURYL SULFATE (UNII: 368GB5141J)			
<b>Product Characteristics</b>				
<b>Color</b>	pink	<b>Score</b>	no score	
<b>Shape</b>	CAPSULE	<b>Size</b>	14mm	
<b>Flavor</b>		<b>Imprint Code</b>	PH013	
<b>Contains</b>				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:66424-021-01	100 in 1 BOTTLE, PLASTIC		
2	NDC:66424-021-10	1000 in 1 BOTTLE, PLASTIC		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
OTC monograph final	part341	01/27/2010		

**Labeler** - SDA Laboratories, Inc. (948067889)

**Registrant** - Pharbest Pharmaceuticals, Inc. (557054835)

### Establishment

Name	Address	ID/FEI	Business Operations
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Revised: 11/2011

SDA Laboratories, Inc.