

**DIPHENHYDRAMINE HCL- diphenhydramine hcl capsule**  
**Blenheim Pharmacal, 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.*

-----

**Drug Facts**

**Active ingredient(in each capsule)**

Diphenhydramine HCL 25 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 to 2 capsule
Children 6 to under 12 years	1 capsule
Children under 6 years	ask a doctor

### 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**

### Principal Display Panel

Blenheim Pharmacal, Inc.

**NDC 10544-166-15**

Diphenhydramine HCl Capsules, USP 25mg  
15 Capsules

The image shows the principal display panel for Diphenhydramine HCl Capsules, USP 25mg, 15 Capsules. The panel is rectangular and features a green border. On the left side, there is a vertical barcode with the numbers 1054416615 printed vertically. The main text on the panel includes: NDC: 10544-166-15, LCN#: 00, MFG: 66424-020-10, and the product name 'Diphenhydramine HCl Capsules, USP 25mg 15 Capsules'. Below the product name, there is a dosage instruction: 'Dosage: See package insert'. Storage instructions are provided: 'Store at controlled room temperature 15°-30°C (59°-86°F)'. A warning is included: 'Protect from excessive moisture. Store in a tight, light-resistant container (See USP). Keep out of the reach of children.' A large warning is printed vertically: 'If pregnant or breast-feeding, ask a health professional before use. Do not use with any other product containing Diphenhydramine HCl, including one applied topically.' The manufacturer information is: 'Mfg. By: SDA Laboratories, Inc., Greenwich, CT 06830. Repackaged By: Blenheim Pharmacal, Inc., North Blenheim, NY 12131'. A lot and expiration date are provided: 'Lot #: BP00000000 Exp. Date: 00/00/0000'. On the right side of the panel, there is a barcode and the text 'PEEL HERE' with a downward arrow. Below the panel, there is a repeating pattern of the product information and barcode, with 'PEEL HERE' and an upward arrow on the right side.

## DIPHENHYDRAMINE HCL

diphenhydramine hcl capsule

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:10544-166(NDC:66424-020)
<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>
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
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)	

**Product Characteristics**

<b>Color</b>	pink	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	14mm
<b>Flavor</b>		<b>Imprint Code</b>	PH014
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10544-166-15	15 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/12/2010	

**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 final	part341	05/12/2010	

**Labeler** - Blenheim Pharmacal, Inc. (171434587)**Registrant** - Blenheim Pharmacal, Inc. (171434587)

## Establishment

Name	Address	ID/FEI	Business Operations
Blenheim Pharmacal, Inc.		171434587	repack(10544-166)

Revised: 3/2015

Blenheim Pharmacal, Inc.