

**DIPHENHYDRAMINE HCL- diphenhydramine hcl capsule**  
**Cardinal Health 107, LLC**

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**0835&0836(box unit)-Major**

**Active Ingredient (in each banded capsule)**

Diphenhydramine HCl... 50 mg

**Purpose**

Antihistamine

**Use**

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

**WARNINGS**

**Do not use**

- to make a child sleepy
- with any other product containing diphenhydramine, including one applied topically

**Ask a doctor before use if you have**

- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- difficulty in urination due to enlargement of the prostate gland

**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

- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

### **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 of age and over	1 capsule
children 6 years to under 12 years of age	Ask a doctor, the proper dosage strength is not available in this package**

\*\*Do not attempt to break capsules. The proper dosage strength and dosing information for children under 12 years of age is available on the 25 mg package.

### **Other Information**

- Store at 20°C – 25°C (68°F – 77°F); excursions permitted to 15° – 30°C (59° – 86°F) [See USP Controlled Room Temperature]
- Protect from moisture
- Contains lactose

### **Inactive Ingredients**

D&C Red #28, FD&C Blue #1, FD&C Red #40, Gelatin, Lactose and Starch.

### **Questions?**

Questions or comments? (800) 616-2471

### **Distributed by**

MAJOR® PHARMACEUTICALS  
17177 N Laurel Park Drive, Suite 233  
Livonia, MI 48152

### **Distributed By:**

**Cardinal Health**

Dublin, OH 43017

L32991870224

**Principal Display Panel**

Diphenhydramine HCl Capsules

50 mg

10 Capsules



Y42

NDC 55154-0661-0

**DIPHENHYDRAMINE HCl**  
**CAPSULES 50 mg**

**10 CAPSULES**

**Antihistamine**

**Drug Facts**

**Active Ingredient (in each banded capsule)**  
Diphenhydramine Hydrochloride 50 mg

**Purpose**  
Antihistamine

**Inactive Ingredients:** D&C red #28, FD&C blue #1, FD&C red #40, gelatin, lactose and starch.

**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

**When using this product** -marked drowsiness may occur -avoid alcoholic drinks -alcohol, sedatives, and tranquilizers may increase drowsiness -use caution when driving a motor vehicle or operating machinery -excitability may occur, especially in children

**Directions**

**-Take every 4 to 6 hours -do not take more than 6 doses in 24 hours**

**adults and children 12 years of age and over 1 capsule**

**children under 12 years of age ask a doctor, the proper dosage strength is not available in this package\*\***

**\*\*Do not attempt to break capsules. The proper dosage strength and dosing information for children under 12 years of age is available on the 25 mg package.**

**STORAGE:** Store at 20° - 25° C (68° - 77° F); excursions permitted to 15° - 30° C (59° - 86° F) [See USP Controlled Room Temperature]

**-protect from moisture -contains lactose**

**Warnings**

**Do not use** -to make a child sleepy -with any other products containing diphenhydramine, including one applied topically

**Ask a doctor before use if you have** -glaucoma -a breathing problem such as emphysema or chronic bronchitis -difficulty in urination due to enlargement of the prostate gland

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

**This Unit Dose package is not child resistant and is Intended for Institutional Use Only. Keep out of reach of children.**

**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.**

**DO NOT USE IF BLISTER UNIT IS BROKEN**

**Distributed by MAJOR® PHARMACEUTICALS**

**17177 N Laurel Park Drive, Suite 233**

**Livonia, MI 48152**

**MFGD By CPC, NY 11788**

**Questions or Comments? (800) 616-2471**

**Distributed by Cardinal Health**

**Dublin, OH 43017**

**L32991870224**

**Lot: Exp:**

**DIPHENHYDRAMINE HCL**

diphenhydramine hcl capsule

**Product Information**

Product Type		HUMAN OTC DRUG	Item Code (Source)		NDC:55154-0661(NDC:0904-2056)	
Route of Administration		ORAL				
Active Ingredient/Active Moiety						
Ingredient Name				Basis of Strength		Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)				DIPHENHYDRAMINE HYDROCHLORIDE		50 mg
Inactive Ingredients						
Ingredient Name					Strength	
D&C RED NO. 28 (UNII: 767IP0Y5NH)						
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)						
FD&C RED NO. 40 (UNII: WZB9127XOA)						
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)						
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)						
STARCH, CORN (UNII: O8232NY3SJ)						
Product Characteristics						
Color		PINK (red center band)	Score		no score	
Shape		CAPSULE	Size		14mm	
Flavor			Imprint Code		CPC;836	
Contains						
Packaging						
#	Item Code	Package Description		Marketing Start Date		Marketing End Date
1	NDC:55154-0661-0	10 in 1 BAG		01/02/2009		
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product				
Marketing Information						
Marketing Category		Application Number or Monograph Citation		Marketing Start Date		Marketing End Date
OTC Monograph Drug		M017		01/02/2009		

**Labeler** - Cardinal Health 107, LLC (118546603)