

DIPHENHYDRAMINE HCL- diphenhydramine hcl capsule
Cardinal Health 107, LLC

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

L32991870524

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)	Purpose
Diphenhydramine Hydrochloride 50 mg	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 -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 in a dry place at 15° - 30°C (59° - 86°F)

-protect from moisture -contains lactose

Warnings

Do not use -to make a child sleepy -with any other products containing diphenhydramine, even one used on skin

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 (1-800-222-1222) right away.

DO NOT USE IF BLISTER UNIT IS TORN, BROKEN, OR SHOWS ANY SIGNS OF TAMPERING. DO NOT USE IF RED CAPSULE BAND IS BROKEN OR MISSING.

Questions or Comments? 1-800-231-4670

Distributed by MAJOR® PHARMACEUTICALS

Indianapolis, IN 46268

(800) 616-2471

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Distributed by Cardinal Health

Dublin, OH 43017

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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	M012	01/02/2009	

Labeler - Cardinal Health 107, LLC (118546603)