

DIPHENHYDRAMINE HCL- diphenhydramine hcl capsule
Cardinal Health 107, LLC

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 banded capsule)

Diphenhydramine Hydrochloride 50 mg

Purpose

Antihistamine

Keep Out of Reach of Children

Keep out of reach of children.

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.

Warnings

Ask a doctor before use if you have glaucoma, a breathing problem such as emphysema or chronic bronchitis, trouble urinating due to an enlarged prostate gland.

This package is intended for institutional use only. Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers. 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 to 6 hours- do not take more than 6 doses in 24 hours

adults and children 12 years of age and over	1 capsule
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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 - 25C (68-77F); excursions permitted to 15 - 30C (59-86F) [See USP Controlled Room Temperature]

Protect from moisture

- contains lactose

DO NOT USE IF BLISTER UNIT IS BROKEN

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 an enlargement of the prostate gland

Inactive ingredients

D&C Red No.28, FD&C Blue No.1, FD&C Red No.40, Gelatin, Lactose and Starch

Questions or comments? (800) 616-2471

Distributed by

MAJOR® PHARMACEUTICALS

31778 Enterprise Drive

Livonia, MI 48150 USA

MFGD By CPC, NY 11788

Re-Order No. 301575

Distributed By:

Cardinal Health

Dublin, OH 43017

L32991870218

Package/Label 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

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DO NOT USE IF BLISTER UNIT IS BROKEN

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.

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
L32991670218

LOT #: XXXXXXXXXX EXP. DATE: XX/XX/XX

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 not final	part348	01/02/2009	

Labeler - Cardinal Health 107, LLC (118546603)

Revised: 11/2022

Cardinal Health 107, LLC