

DIPHENHYDRAMINE HCL- diphenhydramine hcl capsule
PD-Rx Pharmaceuticals, Inc.

Active Ingredient (in each banded capsule)

Diphenhydramine Hydrochloride 50 mg

Purpose

Antihistamine

Use

Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies

- runny nose
- sneezing
- itchy, watery eyes
- itchy throat and nose
- Temporarily relieves these symptoms due to the common cold
 - runny nose
 - sneezing

WARNINGS

Do not use

- to make a child sleepy
- with any other product 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
- trouble urinating due to an enlarged 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 (800) 222-1222.

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	Take 1 capsule (50 mg)
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.

Other Information

- Store at room temperature, USP.
- Do not use if either capsule band or imprinted safety seal under cap is broken
- 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

16 HOW SUPPLIED

Diphenhydramine HCL capsules are available as follows:

50 mg: pink with red band, capsule, debossed "CPC 836". Available in bottles of

10 capsules (NDC 43063-720-10)

15 capsules (NDC 43063-720-15)

20 capsules (NDC 43063-720-20)

30 capsules (NDC 43063-720-30)

40 capsules (NDC 43063-720-40)

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

<p>Drug Facts</p> <p>Active Ingredient (in each banded capsule) Purpose Diphenhydramine HCl 50 mg Antihistamine</p> <p>Uses Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: • runny nose • sneezing • itchy, watery eyes • itching of the nose or throat • temporarily relieves these symptoms due to the common cold: • runny nose • sneezing</p> <p>Warnings Do not use • to make a child sleepy • with any other product containing diphenhydramine, even one used on skin</p> <p>Ask a doctor before use if you have • a breathing problem such as emphysema or chronic bronchitis • glaucoma • trouble urinating due to an enlarged prostate gland</p> <p>Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers.</p> <p>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</p> <p>GTIN: 00343063720158 SNO: E21C85000003 EXP: 05/2023 LOT: E21C85</p>	<p>NDC 43063-720-15</p>  <p>Diphenhydramine HCL USP 50 mg Complete Allergy Medication</p> <p>Marketed and Packaged By: PD-Rx Pharmaceuticals, Inc Oklahoma City, OK 73127 1-405-942-3040 v.8.19.0</p> <p>15 Capsules TAMPER EVIDENT: DO NOT USE IF SAFETY SEAL IS BROKEN OR MISSING FROM BOTTLE.</p>	<p>Drug Facts (continued)</p> <p>If pregnant or breastfeeding, 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 (800) 222-1222</p> <p>Directions: • take every 4 to 6 hours • do not take more than 6 doses in 24 hours</p> <table border="1"> <tr> <td>Adults and children 12 years of age over</td> <td>take 1 capsule (50mg)</td> </tr> <tr> <td>children under 12 years of age</td> <td>ask a doctor, the proper dosage strength is not available in this package**</td> </tr> </table> <p>**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.</p> <p>Other information • store at room temperature, USP • do not use if either capsule band or imprinted safety seal is broken • protect from moisture • contains lactose</p> <p>Inactive Ingredients D&C red # 28, FD&C blue # 1, FD&C red # 40, gelatin, lactose and starch.</p> <p>Question or comments? 1-800-616-2471</p>	Adults and children 12 years of age over	take 1 capsule (50mg)	children under 12 years of age	ask a doctor, the proper dosage strength is not available in this package**
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DIPHENHYDRAMINE HCL

diphenhydramine hcl capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43063-720(NDC:0904-5307)
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: 7671P0Y5NH)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

GELATIN (UNII: 2G86QN327L)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	pink	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:43063-720-10	10 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2023	
2	NDC:43063-720-20	20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/05/2021	
3	NDC:43063-720-30	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/05/2021	
4	NDC:43063-720-40	40 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/05/2021	
5	NDC:43063-720-15	15 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/18/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	11/02/2009	

Labeler - PD-Rx Pharmaceuticals, Inc. (156893695)

Registrant - PD-Rx Pharmaceuticals, Inc. (156893695)

Establishment

Name	Address	ID/FEI	Business Operations
PD-Rx Pharmaceuticals, Inc.		156893695	repack(43063-720)

Revised: 10/2023

PD-Rx Pharmaceuticals, Inc.