

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

Diphenhydramine HCL

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

Do not use

- to make a child sleepy
- with any other product containing diphenhydramine, even one used on skin

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 in a dry place at 15° - 30°C (59° - 86°F).
- Do not use if either capsule band or imprinted safety seal under cap is broken or missing
- 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?1-800-616-2471

Drug Facts	
Active Ingredient (in each banded capsule)	Purpose
Diphenhydramine HCl 50 mg	Antihistamine
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	
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 • a breathing problem such as emphysema or chronic bronchitis • glaucoma • 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	
 GTIN: 00343063720158 SNO: E21C85000003 EXP: 05/2023 LOT: E21C85	

NDC 43063-720-15



Diphenhydramine

HCL USP 50 mg

Complete Allergy Medication



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Marketed and Packaged By:
 PD-Rx Pharmaceuticals, Inc
 Oklahoma City, OK 73127
 1-405-942-3040 v.8.19.0

15 Capsules

TAMPER EVIDENT: DO NOT USE IF
 SAFETY SEAL IS BROKEN OR MISSING FROM BOTTLE.

Drug Facts (continued)	
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.	
Directions:	
• take every 4 to 6 hours • do not take more than 6 doses in 24 hours	
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**
**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 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.	
Question or comments? 1-800-616-2471	

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: 767IP0Y5NH)	
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
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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:43063-720-15	15 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/18/2021	
3	NDC:43063-720-20	20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/05/2021	
4	NDC:43063-720-30	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/05/2021	
5	NDC:43063-720-40	40 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/05/2021	

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: 8/2024

PD-Rx Pharmaceuticals, Inc.