

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



3 43063 72015 8

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 |
|---|----------|
| 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) | |
| D&C RED NO. 28 (UNII: 7671P0Y5NH) | |

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:43063-720-15 | 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: 10/2025

PD-Rx Pharmaceuticals, Inc.