

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

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**Drug Facts**

**Active ingredient (in each capsule)**

Diphenhydramine HCl 25mg

**Purpose**

Antihistamine

**Uses**

- Temporarily relieves these symptoms associated with the common cold, hay fever, or other respiratory allergies:
  - sneezing
  - itching of the nose or throat
  - runny nose
  - itchy, watery eyes
- Temporarily relieves these symptoms due to common cold:
  - runny nose
  - sneezing

**Warnings**

**Do not use**

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

**Ask a doctor before use if you have**

- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis
- glaucoma

**Ask a doctor or pharmacist before use if you are**

taking sedatives or tranquilizers

**When using this product**

- avoid alcoholic drinks
- marked drowsiness may occur
- excitability may occur, especially in children
- alcohol, sedatives and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

**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 immediately (1-800-222-1222).

**Directions**

- take every 4 to 6 hours, or as directed by a doctor
- do not take more than 6 times in 24 hours
- 12.5 mg dosage strength is not available in this bottle.
- Do not attempt to break capsule.

adults and children 12 years of age and over	25 mg to 50 mg (1-2 capsules)
children 6 to under 12 years of age	12.5 mg**to 25 mg (1 capsule)
children under 6 years of age	Ask a doctor

**Other information**

- **Tamper Evident: Do not use if safety seal under cap is broken or missing**
- store between 20°-25°C (68°-77°F)
- protect from excessive moisture
- use by expiration date on bottle

**Inactive ingredients**

black iron oxide, D&C red #28, D&C blue #1, FD&C red #40, gelatin, lactose monohydrate, magnesium stearate, silicon dioxide, sodium lauryl sulfate

**Questions?**

**Adverse drug event call** (866)562-2756 Mon - Fri 8 AM to 4 PM

**Diphenhydramine HCl 25mg**

Drug Facts	
<b>Active Ingredient</b> (in each banded capsule)	<b>Purpose</b>
Diphenhydramine HCl 25mg	Antihistamine
<b>Uses</b>	
<ul style="list-style-type: none"> <li>Temporarily relieves these symptoms associated with the common cold, hay fever, or other respiratory allergies:</li> <li>sneezing • nasal congestion • runny nose</li> <li>itchy, watery eyes</li> </ul>	
<b>Warnings</b>	
<b>Do not use</b> • to make child sleepy • with any other product containing diphenhydramine, even one used on skin <b>Ask a doctor before use if you have</b> • trouble urinating due to an enlarged prostate gland • a breathing problem such as emphysema, or chronic bronchitis • glaucoma <b>Ask a doctor or pharmacist before use if you are</b> taking sedatives or tranquilizers <b>When using this product</b> • avoid alcoholic drinks • marked drowsiness may occur • excitability may occur, especially in children • alcohol, sedatives and tranquilizers may increase drowsiness • be careful when driving a motor vehicle or operating machinery <b>If pregnant or breast-feeding</b> , ask a health professional before use.	

NDC 55289-479-30



**diphenhydramine  
HCl 25 mg  
Antihistamine**

30 Capsules

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

Marketed and Packaged By:  
PD-Rx Pharmaceuticals, Inc  
Oklahoma City, OK 73127  
1-405-942-3040 v.9.19.0

Drug Facts (continued)	
<b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center immediately (800) 222-1222	
<b>Directions:</b>	
• take every 4 to 6 hours • do not exceed 6 doses in 24 hours	
adults and children 12 years of age and over	25 mg to 50 mg (1 to 2 capsules)
children 6 to 12 years of age	12.5 mg** to 25 mg (1 capsule)
children under 6 years of age	ask a doctor
** 12.5 mg dosage strength is not available in this bottle. Do not attempt to break capsule.	
<b>Other information</b>	
• store at controlled room temperature 15°-30°C (59°-86°F) • protect from excessive moisture • use by expiration date on bottle	
<b>Inactive Ingredients:</b> lactose monohydrate, silicon dioxide, magnesium stearate, black iron oxide, gelatin, sodium lauryl sulfate, D&C red #28, FD&C red #40, FD&C blue #1	
<b>Questions? Adverse drug event call:</b> (866) 562-2756	
	GTIN: 00355289479307 SNO: F22E61000001 EXP: 03/2024 LOT: F22E61

## DIPHENHYDRAMINE HCL

diphenhydramine hcl capsule

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55289-479(NDC:16103-348)
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII: 8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>FERROSO FERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>D&amp;C RED NO. 28</b> (UNII: 7671P0Y5NH)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GELATIN, UNSPECIFIED</b> (UNII: 2G86QN327L)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	

## Product Characteristics

<b>Color</b>	pink (PINK (clear) , WHITE (clear) , RED (band))	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	14mm
<b>Flavor</b>		<b>Imprint Code</b>	PH014
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55289-479-10	10 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/27/2021	
2	NDC:55289-479-12	12 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/27/2021	
3	NDC:55289-479-15	15 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/27/2021	
4	NDC:55289-479-20	20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/27/2021	
5	NDC:55289-479-24	24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/27/2021	
6	NDC:55289-479-30	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/11/2018	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M010	02/01/2016	

**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(55289-479)

Revised: 3/2025

PD-Rx Pharmaceuticals, Inc.