

**DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine
hydrochloride capsule
PD-Rx Pharmaceuticals, Inc.**

Drug Facts

Active ingredient (in each capsule)

Diphenhydramine HCl 25 mg

Purpose

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
- 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

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 (1-800-222-1222).

Directions

- take every 4 to 6 hours, or as directed by a doctor
- do not take more than 6 doses in 24 hours

adults and children
 12 years of age and over
 children 6 to
 under 12 years of age
 children under 6 years of age

1 to 2 capsules

1 capsule

do not use this product
 in children under 6 years of age

Other information

☐ store in a dry place at 15° - 30°C (59° - 86°F)

corn starch, D&C red #28, FD&C blue #1, FD&C red #40, gelatin, lactose monohydrate, magnesium stearate, sodium lauryl sulfate

Questions or comments?

1-800-616-2471

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

HOW SUPPLIED: Diphenhydramine HCL capsules are available as follows:

NDC 72789-317-10 Bottles of 10

NDC 72789-317-12 Bottles of 12


NDC 72789-317-15 Bottles of 15

NDC 72789-317-20 Bottles of 20

NDC 72789-317-30 Bottles of 30

Drug Facts	
Active Ingredient (in each capsule)	Purpose
Diphenhydramine HCl 25 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	
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: 00372789317304 SNO: D23A43000005 EXP: 12/2025 LOT: D23A43	

NDC 72789-317-30



**Diphenhydramine
HCL 25 mg**

Marketed and Packaged By
 PD-Rx Pharmaceuticals, Inc
 Oklahoma City, OK 73127
 1-405-942-3040 v.4.4.0

30 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 1 (800) 222-1222	
Directions: • take every 4 to 6 hours, or as directed by a doctor • do not take more than 6 doses in 24 hours	
Adults and children 12 years of age and over	1 to 2 capsules
children 6 to under 12 years of age	1 capsule
children under 6 years of age	do not use this product in children under 6 years of age
Other information • store in a dry place at 15° - 30°C (59° - 86°F)	
Inactive Ingredients corn starch, D&C red # 28, FD&C blue # 1, FD&C red # 40, gelatin, lactose monohydrate, magnesium stearate, sodium lauryl sulfate	
Questions or comments? 1-800-616-2471	
 3 72789 31730 4	

DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72789-317(NDC:0904-7237)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 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)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
GELATIN (UNII: 2G86QN327L)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	pink (Half pink and half clear with white powder inside and sealed with red band)	Score	no score
Shape	CAPSULE	Size	14mm
Flavor		Imprint Code	CPC;835
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72789-317-10	10 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/05/2023	
2	NDC:72789-317-12	12 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/05/2023	
3	NDC:72789-317-15	15 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/05/2023	
4	NDC:72789-317-20	20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/05/2023	
5	NDC:72789-317-30	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/05/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	04/14/2022	

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(72789-317)

Revised: 10/2024

PD-Rx Pharmaceuticals, Inc.