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

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adults and children

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)

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:

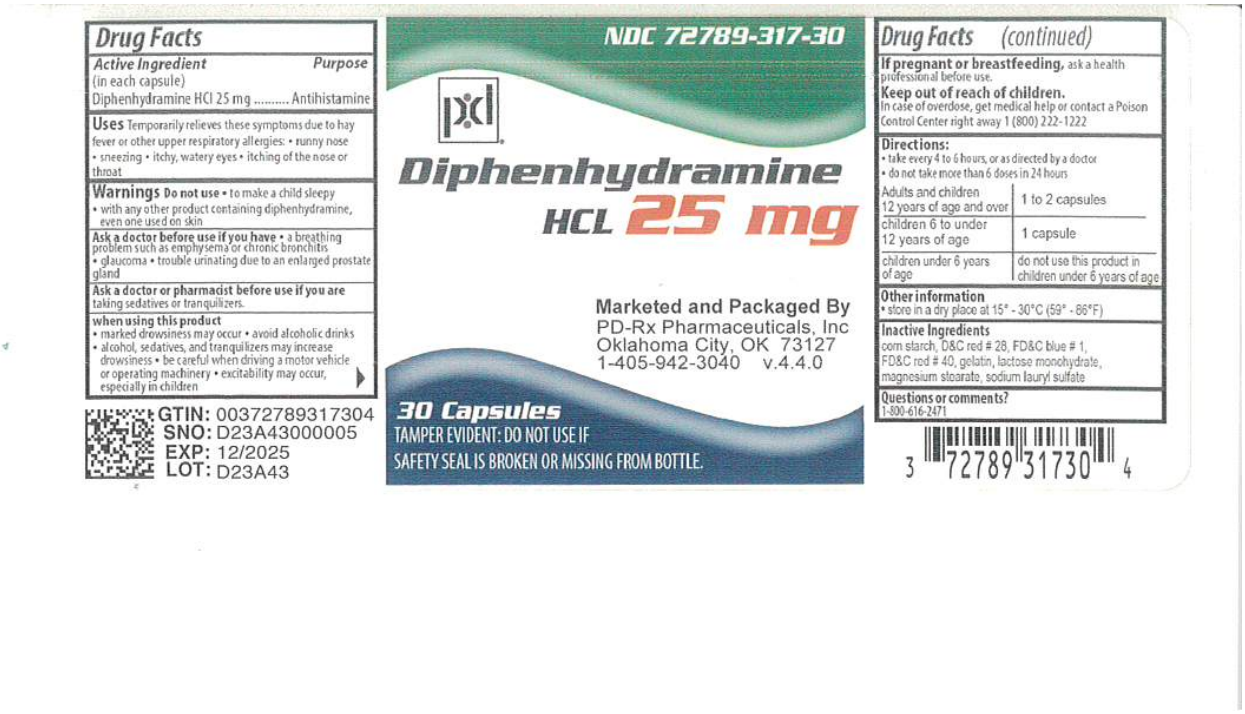
NDC 72789-317-10 Bottles of 10

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



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: 10/2023 PD-Rx Pharmaceuticals, Inc.