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

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 (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 is broken or missing from bottle.**
- store between 20°-25°C (68°-77°F)
- protect from excessive moisture
- use by expiration date on bottle

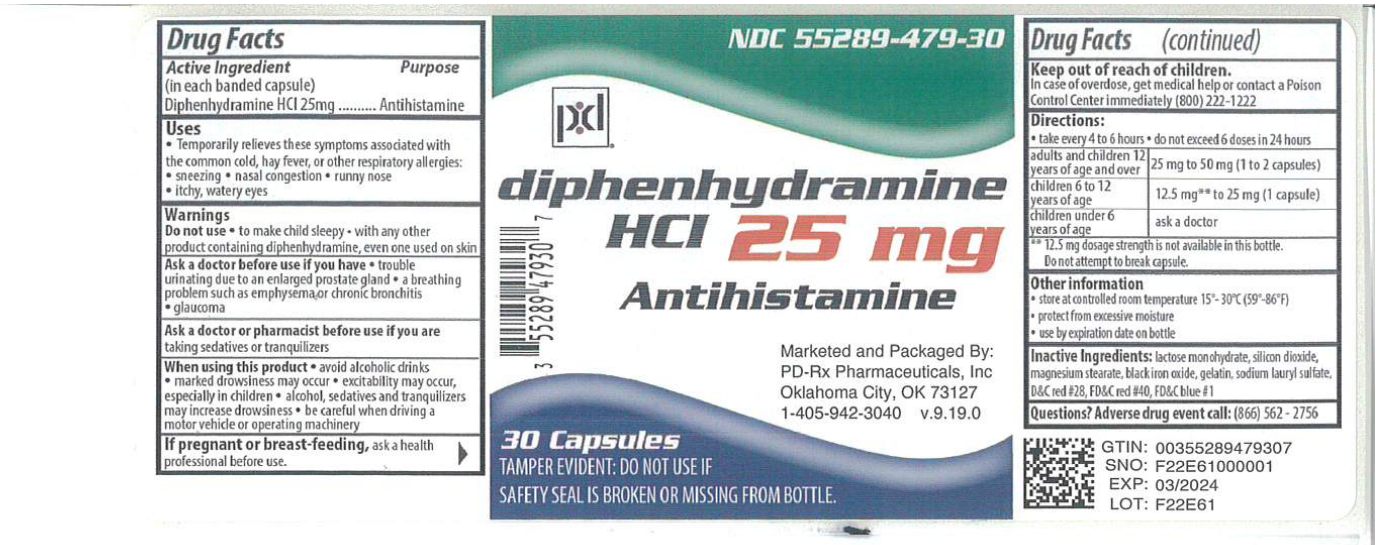
Inactive ingredients

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



DIPHENHYDRAMINE HCL

diphenhydramine hcl capsule

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55289-479(NDC:16103-348)
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**
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

Product Characteristics

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

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	M012	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: 3/2024 PD-Rx Pharmaceuticals, Inc.