

DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine hydrochloride capsule
RedPharm Drug, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Diphenhydramine 25mg

ACTIVE INGREDIENT (IN EACH CAPSULE)

Diphenhydramine HCl 25 mg

PURPOSE

Antihistamine

USES

temporarily relieves these symptoms of hay fever or other upper respiratory allergies:

- runny nose
- sneezing
- itchy nose or throat
- itchy, watery eyes

WARNINGS

☐**Do not use**☐ with any other product containing diphenhydramine, even one used on skin

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

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

☐**Ask a doctor or pharmacist before use if you are**☐ taking sedatives or tranquilizers

☐**When using this product**

- ☐you may get very drowsy
- 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 THE REACH OF CHILDREN.

In case of overdose, get medical help or contact a Poison Control Venter right away.

DIRECTIONS

- adults & children 12 years and over: take 1-2 capsules every 4-6 hours; not more than 6 does in 24 hours

- Children under 12 years: ask a doctor

OTHER INFORMATION

- store at 15°-30°C (59°-86°F)
- protect from moisture
- This is a bulk package. Dispense contents in a tight, light-resistant container with a child-resistant closure as defined in the USP

INACTIVE INGREDIENTS

benzyl alcohol, butylparaben, D&C red #28, edible black ink, FD&C blue #1, FD&C red #40, gelatin, lactose, magnesium stearate, methylparaben, polysorbate 80, propylparaben, sodium lauryl sulfate

QUESTIONS OR COMMENTS?

call 1-888-374-2791, 8:30 am - 4:30 pm ET, Monday - Friday

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP OR BAND AROUND ANY CAPSULE IS MISSING OR DAMAGED

Distributed by:

Epic Pharma, LLC

Laurelton, NY

11413

PACKAGE LABEL. PRINCIPAL DISPLAY PANEL

NDC: 67296-1645-1
DIPHENHYDRAMINE HCL
 25MG
 24 Capsules

Rx Only


Lot: 17J354 1 Exp: 09/19

Usual adult dosage: See package insert
 Store at controlled room temperature: 20-25 C (68-77 F)

Mfg By: Epic Pharma LLC
 Laurelton NY 11413
 42806-648-10

Dist. by: Redpharm Drug Eden Prairie, MN 55344

SIN 156206



DIPHENHYDRAMINE HYDROCHLORIDE			
diphenhydramine hydrochloride capsule			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67296-1645(NDC:42806-648)
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
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BUTYLPARABEN (UNII: 3QPIIU3FV8)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
LACTOSE (UNII: J2B2A4N98G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

Product Characteristics

Color	pink	Score	no score
Shape	CAPSULE	Size	14mm
Flavor		Imprint Code	AP;020
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67296-1645-1	24 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/01/2019	

Labeler - RedPharm Drug, Inc. (828374897)**Establishment**

Name	Address	ID/FEI	Business Operations
RedPharm Drug, Inc.		828374897	repack(67296-1645) , relabel(67296-1645)