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

- Iglaucoma
- 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 tranqulizers

When using this product

- Iyou 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

Ichildren 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 **888-374-279 1**, 8:30 am - 4:30 pm ET, Monday - Friday

ITAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFTEY 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 17J354 1

Usual adult dosage: See package insert

Lot:

Store at controlled room temperature:

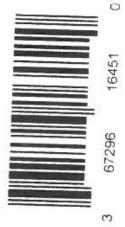
20-25 C (68-77 F) Mfg By: Epic Pharma LLC

Laurelton NY 11413

42806-648-10 Dist. by: Redpharm Drug Eden Prairie, MN 55344

SIN 156206

Exp: 09/19



DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride capsule

Rx Only

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 HYDRO CHLO RIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients	
Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
D&C RED NO. 28 (UNII: 767IP0 Y5NH)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
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				

l	Packaging			
l	# 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		0 1/0 1/20 19		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	0 1/0 1/20 19		

Labeler - RedPharm Drug, Inc. (828374897)

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

Revised: 1/2021 RedPharm Drug, Inc.