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

DRUG FACTS

.

ACTIVE INGREDIENT

(in each capsule)

Diphenhydramine HCl 25 mg

PURPOSE

Antihistamine

INDICATIONS & USAGE

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

runny nose
itchy nose or throat
sneezing
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 & 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.

DIRECTIONS

adults and children 12 years and over: take 1 to 2 capsules every 4-6 hours; not more than 6 doses in 24 hours
children under 12 years: ask a doctor

OTHER INFORMATION

store at 15-30 °C (59-86 °F)
protect from moisture
For 1000 Count: 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 bule #1, FD&C red# 40, gelatin, lactose, magnesium stearate, methylparaben, polysorbate 80, propylparaben, sodium laurel sulfate

QUESTIONS OR COMMENTS

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

Distributed by: Qualitest Pharmaceuticals, Inc.

DOSAGE & ADMINISTRATION

adults and children 12 years and over: take 1 to 2 capsules every 4-6 hours; not more than 6 doses in 24 hours
children under 12 years: ask a doctor

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC: 67296-1055-1
DIPHENHYDRAMINE HCL

Rx Only

25MG
24 Capsules

Lot: 13D215 1 Exp: 04/15

Usual adult dosage: See package insert
Store at controlled room temperature: 15-30 C (59-86 F)

Mfg. for: Qualitest Pharmaceuticals Inc
Huntsville, AL 35811
0603-3339-32

Dist. by: Redpharm Drug Eden Prairie, MN 55344

LCN: 539186

DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride capsule

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67296-1055(NDC:0603-3339)
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**
MAGNESIUM STEARATE (UNII: 70097M6I30)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
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:67296-1055-1	24 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/01/2018	

Labeler - RedPharm Drug, Inc. (828374897)

Establishment

Name	Address	ID/FEI	Business Operations
RedPharm Drug, Inc.		828374897	repack(67296-1055) , relabel(67296-1055)

Revised: 1/2020 RedPharm Drug, Inc.