

**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.*

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**diph**

**ACTIVE INGREDIENT (IN EACH BANDED CAPSULE)**

Diphenhydramine HCl... 25 mg

Diphenhydramine HCl... 50 mg

**PURPOSE**

Antihistamine

**USE**

25 MG

Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

runny nose  
sneezing  
itchy, watery eyes  
itchy throat and nose

Temporarily relieves these symptoms due to the common cold:

runny nose  
sneezing

50 MG

Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies and common cold

sneezing  
runny nose  
itchy, watery eyes  
itchy throat and nose

Do not use

25 MG

to make a child sleepy  
with any other product containing diphenhydramine, even one used on skin

50 MG

to make a child sleepy  
with any other product containing diphenhydramine, including one applied topically

**ASK A DOCTOR BEFORE USE IF YOU HAVE**

25 MG

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

50 MG

glaucoma  
a breathing problem such as emphysema or chronic bronchitis  
difficulty in urination due to enlargement of the 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.

### **DIRECTIONS**

Take every 4-6 hours  
Do not take more than 6 doses in 24 hours

25 MG

adults and children 12 years of age and over 1 to 2 capsules  
children 6 years 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

50 MG

adults and children 12 years of age and over 1 capsule  
children 6 years to under 12 years of age Ask a doctor, the proper dosage strength is not available in this package\*\*

\*\*Do not attempt to break capsules. The proper dosage strength and dosing information for children under 12 years of age is available on the 25 mg package.

### **OTHER INFORMATION**

Store at 20°C – 25°C (68°F – 77°F); excursions permitted to 15° – 30°C (59° – 86°F) [See USP Controlled Room Temperature]

Protect from moisture

Contains lactose

**INACTIVE INGREDIENTS**

D&C Red #28, FD&C Blue #1, FD&C Red #40, Gelatin, Lactose and Starch.

**QUESTIONS?**

Questions or comments? (800) 616-2471

**DISTRIBUTED BY**

MAJOR® PHARMACEUTICALS  
17177 N Laurel Park Drive, Suite 233,  
Livonia, MI 48152

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

NDC: 67296-1042-1  
**DIPHENHYDRAMINE HCL**  
25MG

Rx Only

24 Capsules  
Lot: 132549 1

Exp: 02/16

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

Mfg. for: Major Pharmaceuticals  
Livonia, MI 48150  
0904-5336-80

Dist. by: Redpharm Drug Eden Prairie, MN 55344

LCN: 531219



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**DIPHENHYDRAMINE HYDROCHLORIDE**

diphenhydramine hydrochloride capsule

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:67296-1042(NDC:0904-5306)
<b>Route of Administration</b>	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
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)	
STARCH, CORN (UNII: O8232NY3SJ)	
GELATIN (UNII: 2G86QN327L)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

### Product Characteristics

<b>Color</b>	pink (half pink and half clear with white powder inside, banded in red around the middle)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	14mm
<b>Flavor</b>		<b>Imprint Code</b>	cpc;835
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67296-1042-1	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	part336	01/01/2018	

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

### Establishment

Name	Address	ID/FEI	Business Operations
RedPharm Drug, Inc.		828374897	repack(67296-1042) , relabel(67296-1042)

