

**DIPHENHYDRAMINE HYDROCHLORIDE - diphenhydramine hydrochloride capsule  
REMEDYREPACK 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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**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

**WARNINGS**

**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

DRUG: Diphenhydramine Hydrochloride

GENERIC: Diphenhydramine Hydrochloride

DOSAGE: CAPSULE

ADMINISTRATION: ORAL

NDC: 70518-0861-0

COLOR: pink

SHAPE: CAPSULE

SCORE: No score

SIZE: 14 mm

IMPRINT: cpc;836

PACKAGING: 30 in 1 BOTTLE, PLASTIC

ACTIVE INGREDIENT(S):

- DIPHENHYDRAMINE HYDROCHLORIDE 50mg in 1

INACTIVE INGREDIENT(S):

- D&C RED NO. 28
- GELATIN
- LACTOSE
- FD&C BLUE NO. 1
- FD&C RED NO. 40
- STARCH, CORN

# Diphenhydramine HCl

**50 mg Capsule**

QTY: **30**

ID #: cpc;836

NDC #: 70518-0861-00

LOT #:

MFG: Major Pharma, Livonia, MI 48150

**Expires:**

Shape: Capsule

Ref #: 00904-2056-61

**NOT FOR RETAIL SALE**

**Directions For Use: See Package Insert**

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

Repackaged by:

RemedyRepack Inc., Indiana, PA 15701, 1-724-465-8762



## DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride capsule

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70518-0861(NDC:0904-2056)
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	50 mg

### Inactive Ingredients

Ingredient Name	Strength
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
LACTOSE (UNII: J2B2A4N98G)	
STARCH, CORN (UNII: O8232NY3SJ)	

## Product Characteristics

<b>Color</b>	pink (pink, 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;836
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70518-0861-0	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/22/2017	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part336	11/22/2017	

**Labeler** - REMEDYREPACK INC. (829572556)

Revised: 11/2017

REMEDYREPACK INC.