**DIPHENHYDRAMINE HCL- diphenhydramine hcl capsule**
**medsource pharmaceuticals**

*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.*

---

**Drug Facts**

**Active ingredient(in each capsule)**

Diphenhydramine HCL 25 mg

**Purpose**

Antihistamine

**Uses:**

- Temporarily relieves these symptoms associated with the common cold, hay fever, or other respiratory allergies.
- Sneezing.
- Nasal congestion.
- Runny nose.
- Itchy, watery eyes.

**Warnings:**

**Do not use**

- With any other product containing Diphenhydramine HCL, including one applied topically.

**Ask a doctor or pharmacist before use**

If you have

- Trouble urinating due to enlarged prostate gland
- A breathing problem such as emphysema or chronic bronchitis
- Glaucoma
- If you are taking sedatives or tranquilizers

**When using this product**

- Avoid alcoholic drinks.
- Marked drowsiness may occur.
- Excitability may occur, especially in children.
- Alcohol, sedatives and tranquilizers may increase drowsiness.
- Be careful when driving a motor vehicle or operating machinery.

**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.

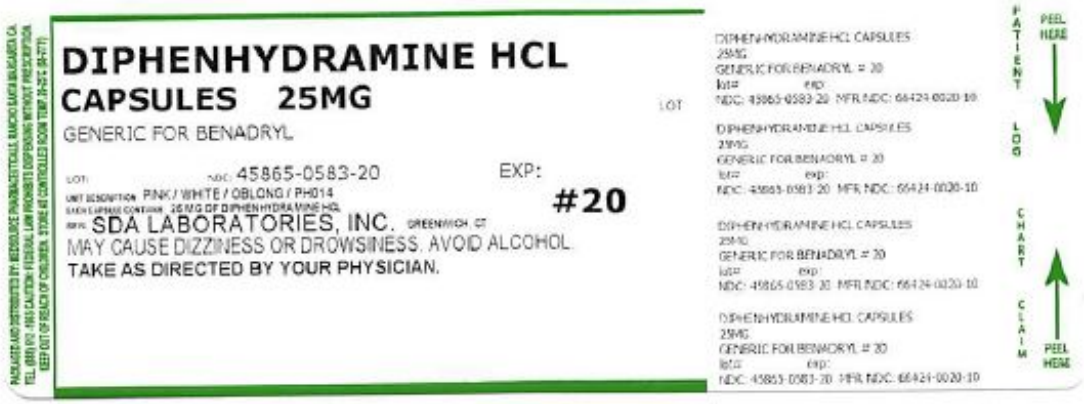
| | |
|---|---|
| Adults and children 12 years or over | 1 to 2 capsule |
| Children 6 to under 12 years | 1 capsule |
| Children under 6 years | ask a doctor |

**Other information:**

- Store at room temperature 15-30 degrees C (59-86 degrees F)
- Protect from excessive moisture

**Inactive ingredients: Black Iron Oxide, D & C Red #28, FD & C Blue #1, FD & C Red #40, Gelatin, Lactose Monohydrate, Magnesium Stearate, Silicon Dioxide, Sodium Lauryl Sulfate**

**Package Label - Bottle of 20**




## DIPHENHYDRAMINE HCL

diphenhydramine hcl capsule

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:45865-583(NDC:66424-020) |
| **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 |
|---|---|
| **FERROSOFERRIC OXIDE** (UNII: XM0M87F357) | |
| **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 MONOHYDRATE** (UNII: EWQ57Q8I5X) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **SODIUM LAURYL SULFATE** (UNII: 368GB5141J) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | pink | **Score** | no score |
| **Shape** | CAPSULE | **Size** | 14mm |
| **Flavor** | | **Imprint Code** | PH014 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:45865-583-20 | 20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 06/01/2018 | |
| **2** | NDC:45865-583-30 | 30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 06/01/2018 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph final | part341 | 01/27/2010 | |

## Labeler - medsource pharmaceuticals (833685915)

## Registrant - Pharbest Pharmaceuticals, Inc. (557054835)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| medsource pharmaceuticals | | 833685915 | repack(45865-583) |

Revised: 12/2018 medsource pharmaceuticals