

**DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine hydrochloride capsule**  
**Epic Pharma, LLC**

*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 HYDROCHLORIDE CAPSULES, USP 25 mg**

**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**

- ☐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 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

- Children 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 1-888-374-2791, 8:30 am - 4:30 pm ET, Monday - Friday

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY 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 - 25 MG

Diphenhydramine HCl Capsules, USP 25 mg

ANTI-HISTAMINE

1000 Capsules

**THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN**

|   |  |   |  |
|---|--|---|--|
| NDC 42806-648-10  |  | THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN                                  |  |
| *Compare to active ingredient in BENADRYL® Allergy  |  |   |  |
| <b>Diphenhydramine HCl</b><br>Capsules, USP   |  |   |  |
| <b>25 mg</b>  |  |   |  |
| <b>ANTI-HISTAMINE</b>   |  |   |  |
| <b>1000 Capsules</b>  |  |   |  |
| Distributed by:<br>Epic Pharma, LLC<br>Laurelton, NY 11413  |  |  |  |
| <b>Drug Facts</b>   |  |   |  |
| <b>Active ingredient (in each capsule)</b><br>Diphenhydramine HCl 25 mg   |  | <b>Purpose</b><br>Antihistamine   |  |
| <b>Uses</b><br>temporarily relieves these symptoms of hay fever or other upper respiratory allergies:<br><ul style="list-style-type: none"> <li>■ runny nose</li> <li>■ itchy nose or throat</li> <li>■ sneezing</li> <li>■ itchy, watery eyes</li> </ul>   |  |   |  |
| <b>Warnings</b><br>Do not use with any other product containing diphenhydramine, even one used on skin.<br><b>Ask a doctor before use if you have</b><br><ul style="list-style-type: none"> <li>■ glaucoma</li> <li>■ trouble urinating due to an enlarged prostate gland</li> <li>■ a breathing problem such as emphysema or chronic bronchitis</li> </ul> |  |   |  |
| <b>Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers</b>   |  |   |  |
| <b>When using this product</b><br><ul style="list-style-type: none"> <li>■ you may get very drowsy</li> <li>■ avoid alcoholic drinks</li> <li>■ alcohol, sedatives and tranquilizers may increase drowsiness</li> <li>■ be careful when driving a motor vehicle or operating machinery</li> <li>■ excitability may occur, especially in children</li> </ul> |  |   |  |
| <b>if pregnant or breast-feeding</b> , ask a health professional before use.<br><b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away.  |  |   |  |
| <b>Directions</b><br><ul style="list-style-type: none"> <li>■ take every 4-6 hours</li> <li>■ do not take more than 6 doses in 24 hours</li> <li>adults &amp; children 12 years and over 1-2 capsules</li> <li>children under 12 years ask a doctor</li> </ul>  |  |   |  |
| <b>Other information</b><br><ul style="list-style-type: none"> <li>■ store at 15°-30°C (59°-86°F)</li> <li>■ protect from moisture</li> </ul>   |  |   |  |
| This is a bulk package. Dispense contents in a tight, light-resistant container with a child-resistant closure as defined in the USP  |  |   |  |
| <b>Inactive ingredients</b><br>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   |  |   |  |
| <b>Questions or comments?</b> call 888-374-2791, 8:30 am - 4:30 pm ET, Monday - Friday  |  |   |  |
| TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP OR BAND AROUND ANY CAPSULE IS MISSING OR DAMAGED  |  |   |  |
| *Epic Pharma, LLC is not affiliated with the owner of the trademark BENADRYL® Allergy.  |  |   |  |
| LEP 1016  |  | LE3477  |  |
| Lot No.:  |  | 4 2 8 0 6 - 6 4 8 - 1 0 0   |  |
| Exp. Date:  |  | No Varnish  |  |

**DIPHENHYDRAMINE HYDROCHLORIDE**

diphenhydramine hydrochloride capsule

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:42806-648 |
| <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 |
|--|----------|
| BENZYL ALCOHOL (UNII: LKG8494WBH)        |          |
| BUTYL PARABEN (UNII: 3QPI1U3FV8)         |          |
| D&C RED NO. 28 (UNII: 767IP0Y5NH)        |          |
| FD&C BLUE NO. 1 (UNII: HBR47K3TBD)       |          |
| FD&C RED NO. 40 (UNII: WZB9127XOA)       |          |
| GELATIN (UNII: 2G86QN327L)               |          |
| LACTOSE (UNII: J2B2A4N98G)               |          |
| MAGNESIUM STEARATE (UNII: 70097M6I30)    |          |
| METHYL PARABEN (UNII: A2I8C7HI9T)        |          |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H)        |          |
| PROPYL PARABEN (UNII: Z8IX2SC1OH)        |          |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) |          |

### Product Characteristics

|                 |         |                     |          |
|-----------------|---------|---------------------|----------|
| <b>Color</b>    | pink    | <b>Score</b>        | no score |
| <b>Shape</b>    | capsule | <b>Size</b>         | 14mm     |
| <b>Flavor</b>   |         | <b>Imprint Code</b> | AP;020   |
| <b>Contains</b> |         |                     |          |

### Packaging

| # | Item Code        | Package Description                                 | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:42806-648-10 | 1000 in 1 BOTTLE; Type 0: Not a Combination Product | 11/22/2016           |                    |

### Marketing Information

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part341                                  | 11/22/2016           |                    |

**Labeler** - Epic Pharma, LLC (827915443)

