

## **PHARBEDRYL- diphenhydramine hcl 50mg capsule**

**Ulai Health 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.*

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### **Drug Facts**

#### **Active ingredient (in each banded capsule)**

Diphenhydramine HCl 50mg

#### **Purpose**

Antihistamine

#### **Uses**

- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
- runny nose
- sneezing
- itchy, watery eyes
- itching of the nose or throat
- temporarily relieves these symptoms due to common cold:
- runny nose
- sneezing

#### **Warnings**

##### **Do not use**

- with any other product containing diphenhydramine, even one used on skin

##### **Ask a doctor before use if you have**

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

##### **Ask a doctor or pharmacist before use if you are**

taking sedatives or tranquilizers.

##### **When using this product**

- drowsiness may occur

- avoid alcoholic drinks
- alcohol, sedatives & tranquilizers may increase drowsiness
- use caution 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 (1-800-222-1222).

**Directions**

- take every 4 to 6 hours, or as directed by a doctor
- do not exceed 6 doses in 24 hours

|                                       |              |
|---------------------------------------|--------------|
| adults and children 12 years and over | 1 capsule    |
| children under 12 years               | ask a doctor |

**Other information**

- store at 20-25 °C (68-77 °F)

**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

**Questions or comments?**

(866) 562-2756 (Mon- Fri 8 AM to 4 PM EST)

**PHARBEST**

**NDC 73057-347-11**

**Manufactured in the USA**

**PHARBEDRYL**

**Diphenhydramine HCl 50 mg**

**Antihistamine**

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Throat

**1000 CAPSULES**

**PHARBEST**  **Manufactured in the USA**  
**NDC 73057-347-11**

# PHARBEDRYL

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- ◆ Sneezing
- ◆ Itchy, Watery Eyes
- ◆ Runny Nose
- ◆ Itchy Throat

**1000 CAPSULES**



**THIS PACKAGE FOR HOUSEHOLD WITHOUT YOUNG CHILDREN**  
**TAMPER EVIDENT: DO NOT USE IF SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

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**Ask a doctor or pharmacist before use if you are taking** sedatives or tranquilizers.

**When using this product** ■ drowsiness may occur ■ avoid alcoholic drinks ■ alcohol, sedatives and tranquilizers may increase drowsiness ■ use caution when driving a motor vehicle or operating machinery ■ excitability may occur, especially in children

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**Other information**  
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**Inactive ingredients** black iron oxide, D&C red #28, FD&C blue #1, FD&C red #3, hydroxypropyl methylcellulose, magnesium stearate, silicon dioxide, sodium lauryl sulfate

**Questions or comments?** (866) 562-2756 (Mon-Fri 8 AM to 4 PM EST)

Org. 06/19



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Distributed by:  
**ULAI HEALTH LLC.**  
 Alexandria, VA 22312

## PHARBEDRYL

diphenhydramine hcl 50mg capsule

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:73057-347 |
| <b>Route of Administration</b> | ORAL           |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength             | Strength |
|--|-------------------------------|----------|
| <b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40)<br>(DIPHENHYDRAMINE - UNII:8GTS82S83M) | DIPHENHYDRAMINE HYDROCHLORIDE | 50 mg    |

### Inactive Ingredients

| Ingredient Name                                 | Strength |
|---|----------|
| <b>FERROSO FERRIC OXIDE</b> (UNII: XM0M87F357)  |          |
| <b>D&amp;C RED NO. 28</b> (UNII: 767IP0Y5NH)    |          |
| <b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)   |          |
| <b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)   |          |
| <b>GELATIN</b> (UNII: 2G86QN327L)               |          |
| <b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)   |          |
| <b>MAGNESIUM STEARATE</b> (UNII: 70097M6130)    |          |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)       |          |
| <b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J) |          |

### Product Characteristics

|                 |                   |                     |          |
|-----------------|-------------------|---------------------|----------|
| <b>Color</b>    | pink (Pink/ Pink) | <b>Score</b>        | no score |
| <b>Shape</b>    | CAPSULE           | <b>Size</b>         | 14mm     |
| <b>Flavor</b>   |                   | <b>Imprint Code</b> | PH013    |
| <b>Contains</b> |                   |                     |          |

**Packaging**

| # | Item Code        | Package Description  | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:73057-347-11 | 1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 07/02/2019           |                    |
| 2 | NDC:73057-347-08 | 100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product  | 07/02/2019           |                    |

**Marketing Information**

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part341                                  | 07/02/2019           |                    |

**Labeler** - Ulai Health LLC (081181535)

Revised: 1/2022

Ulai Health LLC