

**DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine hydrochloride capsule  
Preferred Pharmaceuticals, 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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**DIPHENHYDRAMINE HYDROCHLORIDE CAPSULES, USP 25mg and 50mg**

**Drug Facts**

.

**Active Ingredient**

**(in each capsule)**

Diphenhydramine HCl 25 mg

Diphenhydramine HCl 50 mg

**Purpose**

Antihistamine

**Uses**

temporarily relieves these symptoms of hay fever or other upper respiratory allergies:

- runny nose
- itchy nose or throat
- sneezing
- 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 & 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**

- **adults and children 12 years and over:** take 1 to 2 capsules every 4-6 hours; not more than 6 doses in 24 hours
- **children under 12 years:** ask a doctor

**Other Information**

Diphenhydramine 25mg

Bottle of 10 - 68788-9697-1

Bottle of 30 - 68788-9697-3

Diphenhydramine 50mg

Bottle of 30 - 68788-9698-3

- store at 15-30 °C (59-86 °F)
- protect from moisture
- 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 laurel sulfate

**Questions or Comments**

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP OR BAND AROUND ANY CAPSULE IS MISSING OR DAMAGED**

**Distributed by: Qualitest Pharmaceuticals, Inc.**

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

**DIPHENHYDRAMINE HYDROCHLORIDE CAPSULE, USP 25 MG**

**ANTIHISTAMINE**

**Diphenhydramine HCl Capsules, USP 25mg**  
 Generic for: Benadryl  
 Active ingredient (in each capsule): Diphenhydramine HCl 25mg..... Antihistamine



CAUTION: Federal law PROHIBITS transfer of this drug to any person other than the patient for whom it was prescribed.

Diphenhydramine HCL Capsules, USP 25mg  
 Qty: Ins:  
 Lot#: Bat#:  
 Prod# (NDC):

Diphenhydramine HCL Capsules, USP 25mg  
 Qty: Ins:  
 Lot#: Bat#:  
 Prod# (NDC):

Diphenhydramine HCL Capsules, USP 25mg  
 Qty: Ins:  
 Lot#: Bat#:  
 Prod# (NDC):

Diphenhydramine HCL Capsules, USP 25mg  
 Qty: Ins:  
 Lot#: Bat#:  
 Prod# (NDC):

Log  
 Chart  
 Billing  
 Patient

**Pkg Size:** Exp Date:  
 Lot#: Batch#:  
 Ins:  
 Mfg: Qualitest Pharmaceuticals,  
 Huntsville, AL  
 Prod#:

**Warning**  
 Store at 15 - 30 C (59 - 86 F). Protect from moisture. 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, or if you are taking sedatives or tranquilizers. Keep this and all medication out of the reach of children. If pregnant or breast-feeding, ask a health professional before use. Capsule is white and pink, imprinted with A 20.



Take \_\_\_ capsule(s) every \_\_\_ hours.  
 Do not drink alcoholic beverages while taking this medicine.  
 May cause drowsiness.

Instrucciones Espanol:  
 Toma \_\_\_ capsula(s) cada \_\_\_ horas.  
 No tome bebidas alcoholicas mientras toma esta medicina.  
 Puede causar somnolencia.

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**  
**DIPHENHYDRAMINE HYDROCHLORIDE CAPSULE, USP 50 MG**  
**ANTI HISTAMINE**

**Diphenhydramine HCl Capsules, USP 50mg**  
 Generic for: Benadryl  
 Each capsule contains: Diphenhydramine HCL 50mg



CAUTION: Federal law PROHIBITS transfer of this drug to any person other than the patient for whom it was prescribed.

Diphenhydramine HCL Capsules, USP 50mg  
 Qty: Ins:  
 Lot#: Bat#:  
 Prod# (NDC):

Diphenhydramine HCL Capsules, USP 50mg  
 Qty: Ins:  
 Lot#: Bat#:  
 Prod# (NDC):

Diphenhydramine HCL Capsules, USP 50mg  
 Qty: Ins:  
 Lot#: Bat#:  
 Prod# (NDC):

Diphenhydramine HCL Capsules, USP 50mg  
 Qty: Ins:  
 Lot#: Bat#:  
 Prod# (NDC):

Log  
 Chart  
 Billing  
 Patient

**Pkg Size:** Exp Date:  
 Lot#: Batch#:  
 Ins:  
 Mfg: Qualitest Pharmaceuticals,  
 Huntsville, AL  
 Prod#:

**Warning**  
 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, or taking sedatives or tranquilizers. Do not use with any other product containing diphenhydramine, even one used on skin. 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. Store at 15 - 30 C (59 - 86 F). Protect from moisture. Capsules are pink, imprinted with 21.



Take \_\_\_ capsule(s) every \_\_\_ hours.  
 Do not drink alcoholic beverages while taking this medicine.  
 May cause drowsiness.

Instrucciones Espanol:  
 Toma \_\_\_ capsula(s) cada \_\_\_ horas.  
 No tome bebidas alcoholicas mientras toma esta medicina.  
 Puede causar somnolencia.

| DIPHENHYDRAMINE HYDROCHLORIDE          |  |                               |                               |
|--|--|-------------------------------|-------------------------------|
| diphenhydramine hydrochloride capsule  |  |                               |                               |
| <b>Product Information</b>             |  |                               |                               |
| <b>Product Type</b>                    | HUMAN OTC DRUG   | <b>Item Code (Source)</b>     | NDC:68788-9697(NDC:0603-3339) |
| <b>Route of Administration</b>         | ORAL   |                               |                               |
| <b>Active Ingredient/Active Moiety</b> |  |                               |                               |
|  | <b>Ingredient Name</b>   | <b>Basis of Strength</b>      | <b>Strength</b>               |
|  | DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M) | DIPHENHYDRAMINE HYDROCHLORIDE | 25 mg                         |
| <b>Inactive Ingredients</b>            |  |                               |                               |

| Ingredient Name                          | Strength |
|--|----------|
| BENZYL ALCOHOL (UNII: LKG8494WBH)        |          |
| BUTYLPARABEN (UNII: 3QP1U3FV8)           |          |
| 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)    |          |
| METHYLPARABEN (UNII: A2I8C7HI9T)         |          |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H)        |          |
| PROPYLPARABEN (UNII: Z8IX2SC1OH)         |          |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) |          |

### Product Characteristics

|          |         |              |          |
|----------|---------|--------------|----------|
| Color    | PINK    | Score        | no score |
| Shape    | CAPSULE | Size         | 14mm     |
| Flavor   |         | Imprint Code | AP;020   |
| Contains |         |              |          |

### Packaging

| # | Item Code        | Package Description                               | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:68788-9697-1 | 10 in 1 BOTTLE; Type 0: Not a Combination Product |                      |                    |
| 2 | NDC:68788-9697-3 | 30 in 1 BOTTLE; Type 0: Not a Combination Product |                      |                    |

### Marketing Information

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part341                                  | 03/19/2013           |                    |

## DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride capsule

### Product Information

|                         |                |                    |                               |
|-------------------------|----------------|--------------------|-------------------------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:68788-9698(NDC:0603-3340) |
| 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 |
|--|----------|
| BENZYL ALCOHOL (UNII: LKG8494WBH)        |          |
| BUTYLPARABEN (UNII: 3QP1U3FV8)           |          |
| 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)    |          |
| METHYLPARABEN (UNII: A2I8C7HI9T)         |          |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H)        |          |
| PROPYLPARABEN (UNII: Z8IX2SC1OH)         |          |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) |          |

## Product Characteristics

|          |         |              |          |
|----------|---------|--------------|----------|
| Color    | PINK    | Score        | no score |
| Shape    | CAPSULE | Size         | 14mm     |
| Flavor   |         | Imprint Code | AP;021   |
| Contains |         |              |          |

## Packaging

| # | Item Code        | Package Description                               | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:68788-9698-3 | 30 in 1 BOTTLE; Type 0: Not a Combination Product |                      |                    |

## Marketing Information

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part341                                  | 03/19/2013           |                    |

**Labeler** - Preferred Pharmaceuticals, Inc. (791119022)

**Registrant** - Preferred Pharmaceuticals, Inc. (791119022)

## Establishment

| Name                            | Address | ID/FEI    | Business Operations            |
|---------------------------------|---------|-----------|--------------------------------|
| Preferred Pharmaceuticals, Inc. |         | 791119022 | REPACK(68788-9697, 68788-9698) |