DIPHENHYDRAMINE HYDROCHLORIDE - diphenhydramine hydrochloride capsule
Qualitest 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.

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DIPHENHYDRAMINE HYDROCHLORIDE CAPSULES, USP 25mg

Drug Facts

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
- 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**

• store at 15-30 °C (59-86 °F)

• protect from moisture

• For 1000 Count: 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 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**
Drug Facts

Active ingredient: Diphenhydramine HCl 25 mg
Purpose: Anthistamine

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.

Drug Facts continued on back of label

Distributed by:
Qualitest Pharmaceuticals, Inc.,
130 Vintage Drive
Huntsville, AL 35811

QT0908
**Drug Facts** (continued)

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

**Other information**
- store at 15-30°C (59-86°F)
- protect from moisture

**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
DIPHENHYDRAMINE HYDROCHLORIDE CAPSULES, USP
25 mg
ANTIHISTAMINE
1000 CAPSULES

Drug Facts
Active ingredient (in each capsule) Purpose
Diphenhydramine HCl 25 mg 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 reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

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

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

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN

Distributed by:
Qualitest Pharmaceuticals, Inc.
130 Vintage Drive
Huntsville, AL 35811
DIPHENHYDRAMINE HYDROCHLORIDE CAPSULE, USP 25 MG
ANTIHISTAMINE
NDC: 0603-3339-21 – 100 COUNT
NDC: 0603-3339-32 – 1000 COUNT (THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN)

### DIPHENHYDRAMINE HYDROCHLORIDE
diphenhydramine hydrochloride capsule

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<th><strong>Product Information</strong></th>
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<td><strong>Product Type</strong></td>
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<td><strong>Route of Administration</strong></td>
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<td><strong>Item Code (Source)</strong></td>
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<tr>
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<td><strong>Ingredient Name</strong></td>
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<td>DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)</td>
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<td>D&amp;C RED NO. 28 (UNII: 767IP0Y5NH)</td>
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**Marketing Information**

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**Labeler** - Qualitest Pharmaceuticals (011103059)

**Establishment**

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<th>Name</th>
<th>Address</th>
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<tr>
<td>Advance Pharmaceutical, Inc.</td>
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Revised: 11/2012

Qualitest Pharmaceuticals