

DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine hydrochloride capsule
Qualites t 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.

DIPHENHYDRAMINE HYDROCHLORIDE CAPSULES, USP 50mg

Drug Facts

.

Active Ingredient

(in each capsule)

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

- 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 lauryl 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

Qualitest®

100 CAPSULES

ANTIHISTAMINE

50 mg

**DIPHENHYDRAMINE
HYDROCHLORIDE
CAPSULES, USP**

NDC 0603-3340-21

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

Drug Facts

<i>Active ingredient (in each capsule)</i>	<i>Purpose</i>
--	----------------

Diphenhydramine HCl 50 mg	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.

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 capsule 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

Qualitest[®]

1000 CAPSULES

ANTIHISTAMINE

50 mg

DIPHENHYDRAMINE
HYDROCHLORIDE
CAPSULES, USP

NDC 0603-3340-32

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

Drug Facts

Active ingredient (in each capsule)

Diphenhydramine HCl 50 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 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 capsule |
| 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

**THIS PACKAGE FOR
HOUSEHOLDS WITHOUT
YOUNG CHILDREN**

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



010908

DIPHENHYDRAMINE HYDROCHLORIDE CAPSULE, USP 50 MG**ANTI-HISTAMINE****NDC: 0603-3340-21 – 100 COUNT****NDC: 0603-3340-32 – 1000 COUNT (THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN)****DIPHENHYDRAMINE HYDROCHLORIDE**

diphenhydramine hydrochloride capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	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)	
BUTYL PARABEN (UNII: 3QP1IU3FV8)	
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

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:0603-3340-21	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/24/2007	06/30/2018
2	NDC:0603-3340-32	1000 in 1 BOTTLE; Type 0: Not a Combination Product	05/24/2007	06/30/2018

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	05/24/2007	06/30/2018

Labeler - Qualitest Pharmaceuticals (011103059)

Establishment

Name	Address	ID/FEI	Business Operations
Advance Pharmaceutical, Inc.		078301063	MANUFACTURE(0603-3340)

Revised: 11/2012

Qualitest Pharmaceuticals