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.

DIPHENHYDRAMINE HYDROCHLORIDE CAPSULES, USP 50mg

Drug Facts

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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 bule #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

Qualitest®

NDC 0603-3340-21

DIPHENHYDRAMINE HYDROCHLORIDE CAPSULES, USP 50 mg

ANTIHISTAMINE

100 CAPSULES

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

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Drug Facts continued on back of label

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

QT0908

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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®

NDC 0603-3340-32

DIPHENHYDRAMINE HYDROCHLORIDE CAPSULES, USP

50 mg

ANTIHISTAMINE

1000 CAPSULES

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

Drug Facts

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

Other information
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- 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

N 3 0603-3340-32 9

QT0908

DIPHENHYDRAMINE HYDROCHLORIDE CAPSULE, USP 50 MG

ANTIHISTAMINE

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 LABEL	**Item Code (Source)**	NDC:0603-3340
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DIPHENHYDRAMINE HYDROCHLORIDE (DIPHENHYDRAMINE)	DIPHENHYDRAMINE HYDROCHLORIDE	50 mg

Inactive Ingredients	
Ingredient Name	**Strength**
BENZYL ALCOHOL	
BUTYLPARABEN	
D&C RED NO. 28	
FD&C BLUE NO. 1	
FD&C RED NO. 40	
GELATIN	
LACTOSE	
MAGNESIUM STEARATE	
METHYLPARABEN	
POLYSORBATE 80	
PROPYLPARABEN	
SODIUM LAURYL SULFATE	

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		

2	NDC:0603-3340-32	1000 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/24/2007	

Labeler - Qualitest Pharmaceuticals (011103059)

Revised: 11/2012 Qualitest Pharmaceuticals