

DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine hydrochloride capsule
A-S Medication Solutions

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 25mg

Drug Facts

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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 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.

Diphenhydramine Hydrochloride


NDC 50090-0046-0
 A-S Medication Solutions, LLC
Product No. 3504-0
LOT
DIPHENHYDRAMINE
HYDROCHLORIDE
25 MG

EACH CAPSULE CONTAINS
 DIPHENHYDRAMINE HCL 25 MG
 STORE AT 59 TO 86 DEGREES F
 PROTECT FROM MOISTURE

8 CAPSULES

PACKAGED BY:
 A-S Medication Solutions
 Libertyville, IL 60048
SOURCE NDC:
 0603-3339-32
 MFG: QUALITEST PHARMACEUTICAL
 HUNTSVILLE, AL 35811
 SN#

DISCARD AFTER:



DIPHENHYDRAMINE HYDROCHLORIDE
 diphenhydramine hydrochloride capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50090-0046(NDC:0603-3339)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BUTYLPARABEN (UNII: 3QPII03FV8)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
LACTOSE, UNSPECIFIED FORM (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:50090-0046-0	8 in 1 BOTTLE; Type 0: Not a Combination Product	11/28/2014	
2	NDC:50090-0046-1	10 in 1 BOTTLE; Type 0: Not a Combination Product	11/28/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	05/24/2007	

Labeler - A-S Medication Solutions (830016429)

Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-0046) , REPACK(50090-0046)

Revised: 8/2017

A-S Medication Solutions