DIPHENHYDRAMINE HYDROCHLORIDE - diphenhydramine hydrochloride capsule
TYA 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 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

with any other product containing diphenhydramine, even one used on skin **Do not use**

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
  taking sedatives or tranquilizers **Ask a doctor or pharmacist before use if you are**
  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
  ask a health professional before use. **If pregnant or breast-feeding,**

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

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

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

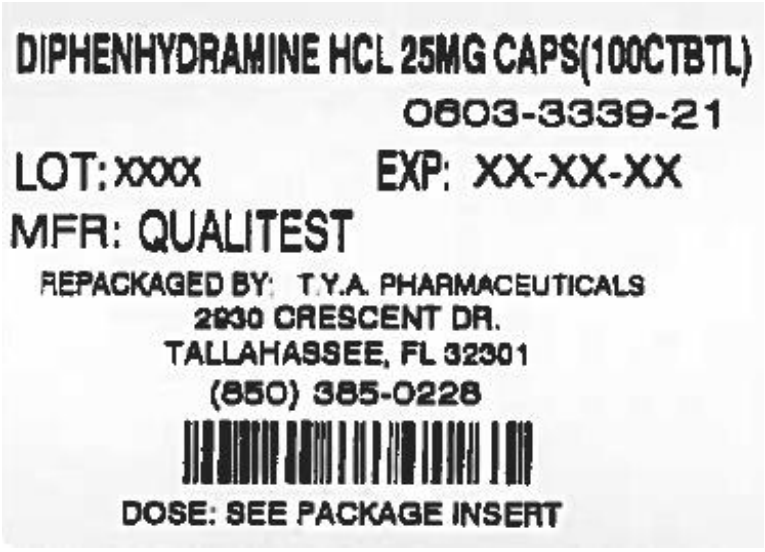
Inactive Ingredients

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.



DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride capsule

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:64725-3339(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: 3QPI1U3FV8)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
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:64725-3339-1	100 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 - TYA Pharmaceuticals (938389038)

Registrant - TYA Pharmaceuticals (938389038)

Establishment

Name	Address	ID/FEI	Business Operations
TYA Pharmaceuticals		938389038	RELABEL(64725-3339) , REPACK(64725-3339)

Revised: 11/2012 TYA Pharmaceuticals