DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine hydrochloride capsule
Epic Pharma, LLC

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 50 mg

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 tranqulizers

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 THE REACH OF CHILDREN.

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

DIRECTIONS

- adults & children 12 years and over: take 1 capsule every 4-6 hours; not more than 6 does in 24 hours

- 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

QUESTIONS OR COMMENTS?

call **888-374-2791**, 8:30 am - 4:30 pm ET, Monday - Friday

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

Distributed by:

Epic Pharma, LLC

Laurelton, NY

11413

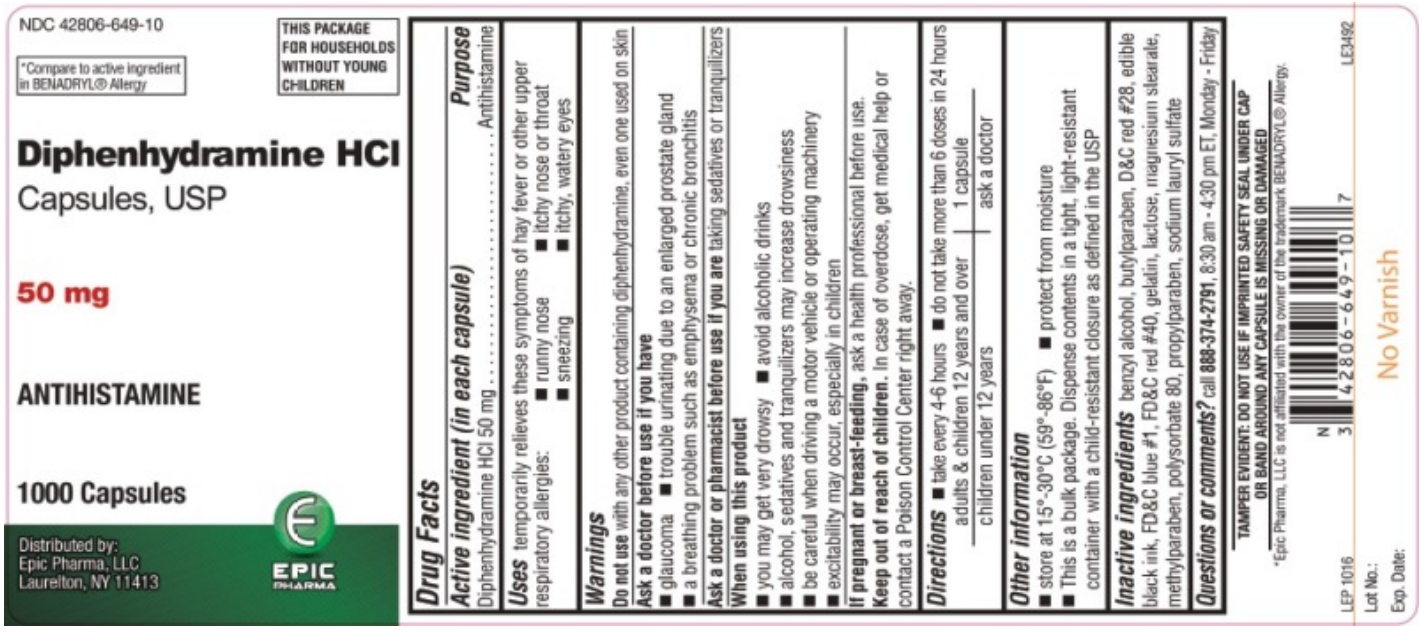
PACKAGE LABEL - PRINCIPAL DISPLAY PANEL - 50 MG

Diphenhydramine HCl Capsules, USP 50 mg

ANTIHISTAMINE

1000 Capsules

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN



DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride capsule

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:42806-649
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)	
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;021
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:42806-649-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	11/22/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	11/22/2016	

Labeler - Epic Pharma, LLC (827915443)