DIPHENHYDRAMINE HCL- diphenhydramine hcl capsule
SDA Laboratories, Inc.

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.

Drug Facts

Active ingredient (in each capsule)

Diphenhydramine HCL 50 mg

Purpose

Antihistamine

Uses:

Temporarily relieves these symptoms associated with the common cold, hay fever, or other respiratory allergies

- sneezing
- nasal congestion
- runny nose
- itchy, watery eyes

Warnings:

Do not use

- With any other product containing Diphenhydramine HCL, including one applied topically.

Ask a doctor or pharmacist before use

If you have

- trouble urinating due to enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- if you are taking sedatives or tranquilizers

When using this product

- avoid alcoholic drinks
- marked drowsiness may occur
- excitability may occur, especially in children
- alcohol, sedatives and tranquilizers may increase drowsiness

- be careful when driving a motor vehicle or operating machinery

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 4-6 hours
- Do not take more than 6 doses in 24 hours.

Adults and children 12 years & over	1 capsule
Children under 12 years	ask a doctor

**25 mg strength is not available in this package. Do not attempt to break capsules.

Other information:

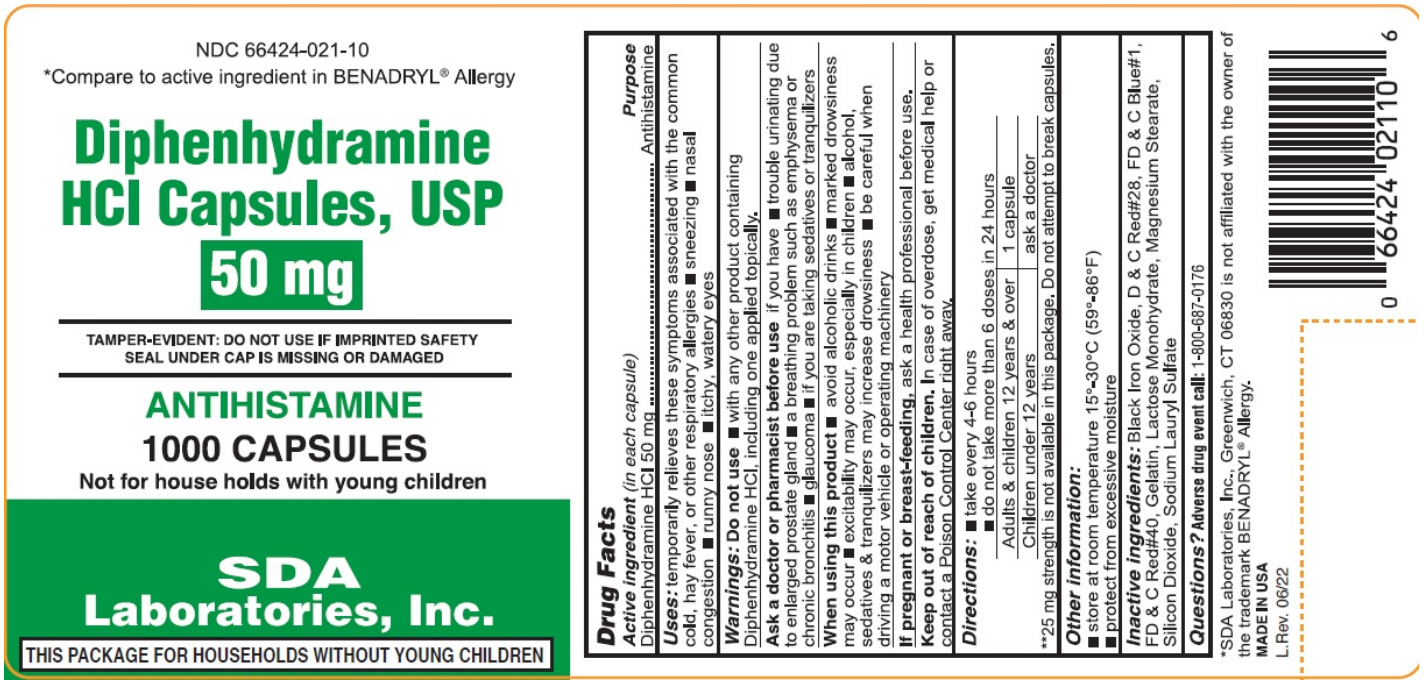
- Store at room temperature 15-30 degrees C (59-86 degrees F)
- Protect from excessive moisture

Inactive ingredients:

Black Iron Oxide, D & C Red #28, FD & C Blue #1, FD & C Red #40, Gelatin, Lactose Monohydrate, Magnesium Stearate, Silicon Dioxide, Sodium Lauryl Sulfate

Questions? Adverse drug event call:

1-800-687-0176



NDC 66424-021-10

*Compare to active ingredient in BENADRYL® ALLERGY

Diphenhydramine

HCl Capsules, USP

50 mg

TAMPER-EVIDENT: DO NOT USE IF IMPRINTED SAFETY

SEAL UNDER CAP IS MISSING OR DAMAGED

ANTIHISTAMINE

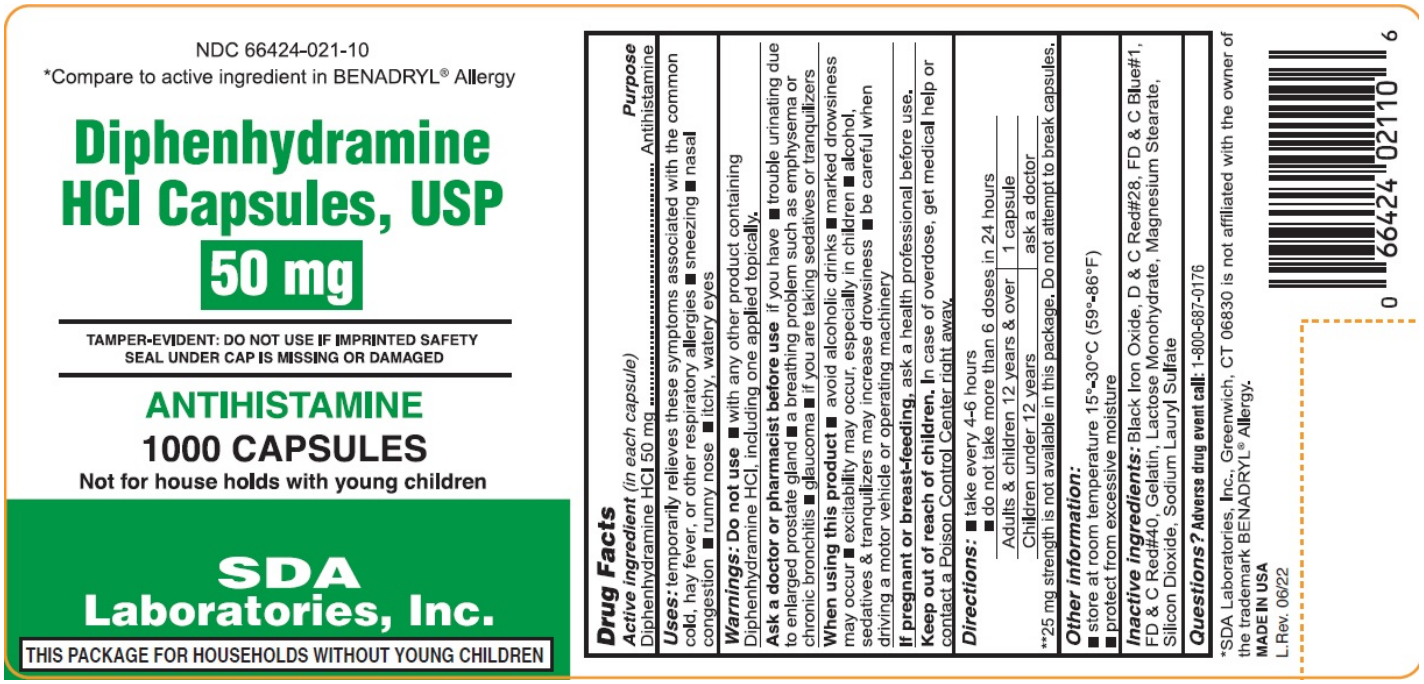
1000 CAPSULES

Not for house holds with young children

SDA

Laboratories, Inc.

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN



DIPHENHYDRAMINE HCL

diphenhydramine hcl capsule

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:66424-021
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**
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
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 MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

Product Characteristics			
Color	pink	**Score**	no score

Shape	CAPSULE	**Size**	14mm
Flavor		**Imprint Code**	PH013
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66424-021-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/27/2010	
2	NDC:66424-021-10	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/27/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/27/2010	

Labeler - SDA Laboratories, Inc. (948067889)

Registrant - Pharbest Pharmaceuticals, Inc. (557054835)

Establishment

Name	Address	ID/FEI	Business Operations
Pharbest Pharmaceuticals, Inc.		557054835	manufacture(66424-021) , analysis(66424-021) , pack(66424-021) , label(66424-021)

Revised: 6/2023 SDA Laboratories, Inc.