

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 25 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

- aAvoid 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 or over	1 to 2 capsule
Children 6 to under 12 years	1 capsule
Children under 6 years	ask a doctor

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

NDC 66424-020-10

*Compare to active ingredient in BENADRYL® Allergy

Diphenhydramine HCl Capsules, USP

25 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

Drug Facts	Purpose
Active ingredient (in each capsule) Diphenhydramine HCl 25 mg	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 & tranquilizers may increase drowsiness ■ be careful when driving a motor vehicle or operating machinery	
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*SDA Laboratories, Inc., Greenwich, CT 06830 is not affiliated with the owner of the trademark BENADRYL® Allergy.
MADE IN USA
L, Rev. 06/22



NDC 66424-020-10

*Compare to active ingredient in BENADRYL® aLLERGY

Diphenhydramine

HCl Capsules, USP

25 mg

TAMPER-EVIDENT: DO NOT USE IF IMPRINTED SAFETY

SEAL UNDER CAP IS MISSING OR DAMAGED

ANTIHISTAMINE

1000 CAPSULES

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SDA

Laboratories, Inc.

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN

NDC 66424-020-10

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Diphenhydramine HCl Capsules, USP

25 mg

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ANTIHISTAMINE 1000 CAPSULES

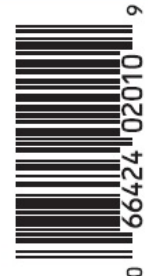
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DIPHENHYDRAMINE HCL

diphenhydramine hcl capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66424-020
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
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
D&C RED NO. 28 (UNII: 7671P0Y5NH)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6130)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

Product Characteristics

Color	pink	Score	no score
Shape	CAPSULE	Size	14mm

Flavor		Imprint Code	PH014	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66424-020-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/27/2010	
2	NDC:66424-020-10	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(66424-020) , analysis(66424-020) , pack(66424-020) , label(66424-020)

Revised: 6/2023

SDA Laboratories, Inc.