ALLERGY RELIEF DIPHENHYDRAMINE HCL 50 MG- diphenhydramine hcl capsule YYBA Corporation

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 banded capsule)

Diphenhydramine HCL 50 mg

Purpose

Antihistamine

Uses:

- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
- runny nose
- sneezing
- itchy, watery eyes
- itching of the nose or throat
- temporarily relieves these symptons due to common cold:
- runny nose
- sneezing

Warnings:

Do not use

- to make a child sleepy
- With any other product containing Diphenhydramine HCL, even one used on skin

Ask a doctor before use if you have

- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers.

When using this product

- marked drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives and tranquilizers may increase drowsiness
- use caution 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 (1-800-222-1222)

Directions:

- take every 4 to 6 hours, or as directed by a doctor
- do not exceed 6 doses in 24 hours

adults and children 12 years and over	1 capsule
children under 12 years	ask a doctor

Other information

Store at 20-25 °C (68-77 °F)

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 or comments?

(866) 933-6337 (Mon-Fri 8 AM to 4 PM EST)

welmate

Compare to active ingredient in BENADRYL® Allergy Extra Strength*

ANTIHISTAMINE

Allergy Relief

Diphenhydramine

HCI Capsules, USP 50 mg

For temporary relief of:

Sneezing

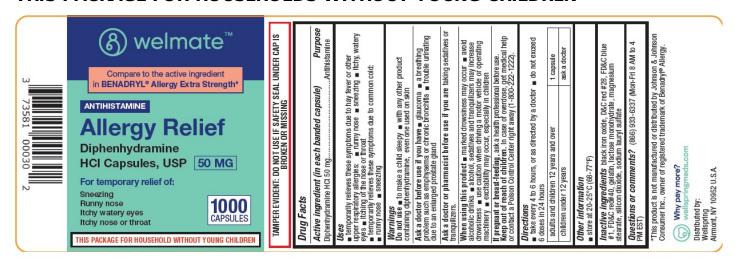
Runny nose

Itchy watery eyes

Itchy nose or throat

1000 CAPSULES

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN



ALLERGY RELIEF DIPHENHYDRAMINE HCL 50 MG

diphenhydramine hcl capsule

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73581-020
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: 368GB5141))			

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:73581- 020-10	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/01/2023	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/01/2023	

Labeler - YYBA Corporation (006339772)

Registrant - Pharbest Pharmaceuticals, Inc. (557054835)

Establishment			
Name	Address	ID/FEI	Business Operations
Pharbest Pharmaceuticals, Inc.		557054835	manufacture(73581-020) , analysis(73581-020) , pack(73581-020) , label(73581-020)

Revised: 8/2023 YYBA Corporation