PHARBEDRYL - diphenhydramine hcl capsule Pharbest Pharmaceuticals, 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 25mg

Purpose

Antihistamine

Uses

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

Warnings

Do not use

- to make child sleepy
- with any other product containing diphenhydramine, even one used on skin

Ask a doctor before use if you have

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

Ask a doctor or pharmacist before use 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 91-800-222-1222).

Directions

- take every 4 to 6 hours, or as directed by a doctor
- do not take more than 6 times in 24 hours

adults and children 12 years and above	1-2 capsules
children 6 to under 12 years	1 capsule
children under 6 years	Ask a doctor

Other information

- Tamper Evident: Do not use if safety seal under cap is broken or missing
- store between 20°-25°C (68°-77°F)
- protect from excessive moisture

Inactive ingredients

black iron oxide, D&C red #28, D&C blue #1, FD&C red #40, gelatin, lactose monohydrate, magnesium stearate, silicon dioxide, sodium lauryl sulfate

Questions?

Adverse drug event call (866)562-2756 Mon - Fri 8 AM to 4 PM

PHARBEST

NDC 16103-0348-11

Manufactured in the USA

* Compare to the active ingredient in Benadryl® Ultratabs

PHARBEDRYL

Diphenhydramine HCI 25mg

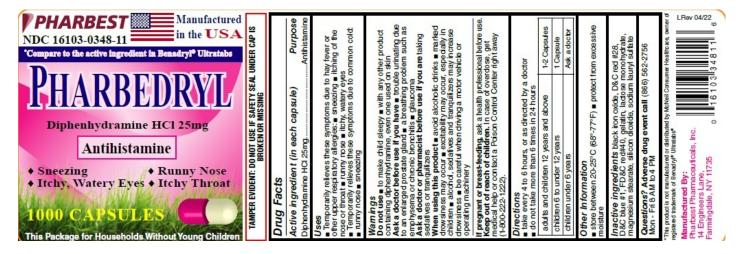
Antihistamine

Sneezing

- Runny Nose
- Itchy, Watery Eyes Itchy Throat

1000 CAPSULES

THIS PACKAGE FOR HOUSEHOLD WITHOUT YOUNG CHILDREN



PHARBEDRYL

diphenhydramine hcl capsule

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:16103-348	

ORAL **Route of Administration**

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			
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, UNSPECIFIED (UNII: 2G86QN327L)				
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
SODIUM LAURYL SULFATE (UNII: 368GB5141J)				

Product Characteristics

Color	pink (PINK (clear) , WHITE (clear) , RED (band))	Score	no score
Shape	CAPSULE	Size	14mm
Flavor		Imprint Code	PH014
Contains			

P	Packaging				
#	Item Code	Package Description Marketing Start Date		Marketing End Date	
1	NDC:16103- 348-03	1 in 1 CARTON	02/01/2016		
1		24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product			
2	NDC:16103- 348-08	1 in 1 CARTON 02/01/2016			
2		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product			
3	NDC:16103- 348-11	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2016		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	02/01/2016	

Labeler - Pharbest Pharmaceuticals, Inc. (557054835)

Registrant - Pharbest Pharmaceuticals, Inc. (557054835)

Establishment			
Name	Address	ID/FEI	Business Operations
Pharbest Pharmaceuticals, Inc.		557054835	analysis(16103-348), manufacture(16103-348), pack(16103-348), label(16103-348)

Revised: 6/2023 Pharbest Pharmaceuticals, Inc.