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 HCI 50mg

Purpose

Antihistamine

Uses

- Temporarily relieves these symptoms due to hay fever or other upper 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 & tranguilizers 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 or as directed by a doctor
- do not take more than 6 doses in 24 hours.

Adults and children 12 years of age &	1 capsule
over	
Children under 12 years of age	Ask a doctor

Other information Tamper Evident:

- do not use if safety seal under the cap is broken or missing
- store at room temperature (15°-30°C)
- 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 16103-0347-08

Manufactured in the USA

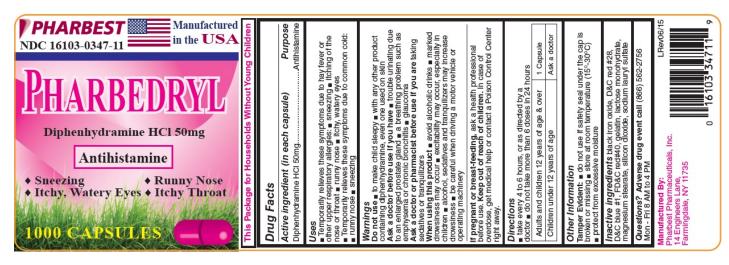
PHARBEDRYL

Diphenhydramine HCI 50mg

Antihistamine

- Sneezing Runny Nose
- Itchy, Watery Eyes
 Itchy Throat

1000 CAPSULES



PHARBEDRYL

diphenhydramine hcl capsule

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:16103-347

Route of Administration ORAL

Active Ingredient/Active Moiety

ricare ingression, realizer locally		
Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40)	DIPHENHYDRAMINE	50 ma

th

(DIPHENHYDRAMINE - UNII:8GTS82S83M)

DIPHENHYDRAMINE - UNII:8GTS82S83M)

50 mg

Inactive Ingredients

ingredient Name	Strengt
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:16103- 347-11	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/11/2006		
2	NDC:16103- 347-08	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/11/2006		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	10/11/2006		

Labeler - Pharbest Pharmaceuticals, Inc. (557054835)

Registrant - Pharbest Pharmaceuticals, Inc. (557054835)

Establishment			
Name	Address	ID/FEI	Business Operations
Pharbest Pharmaceuticals, Inc.		557054835	analysis(16103-347), manufacture(16103-347), pack(16103-347), label(16103-347)

Revised: 1/2021 Pharbest Pharmaceuticals, Inc.