

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 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 & 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 or as directed by a doctor
- do not take more than 6 doses in 24 hours.

Adults and children 12 years of age & over	1 capsule
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 HCl 50mg

Antihistamine

- Sneezing • Runny Nose
 - Itchy, Watery Eyes • Itchy Throat
- 1000 CAPSULES**



PHARBEST
NDC 16103-0347-11

Manufactured
in the **USA**

PHARBEDRYL

Diphenhydramine HCl 50mg

Antihistamine

◆ Sneezing
◆ Runny Nose

◆ Itchy, Watery Eyes
◆ Itchy Throat

1000 CAPSULES



This Package for Households Without Young Children

Drug Facts

Active ingredient (in each capsule) Diphenhydramine HCl 50mg.....Antihistamine

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 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 to 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 & over	1 Capsule	Ask a doctor
Children under 12 years of age		

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

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Manufactured By:
Pharbest Pharmaceuticals, Inc.
14 Engineers Lane,
Farmingdale, NY 11735

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

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	50 mg

Inactive Ingredients

Ingredient Name	Strength
FERROSO FERRIC 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.