

PHARBEDRYL- diphenhydramine hcl capsule

Contract Pharmacy Services-PA

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.

Diphenhydramine 50 mg #30 006

Drug Facts

Active ingredient(in each banded capsule)

Diphenhydramine HCl 50 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, even one used on skin.

Ask a doctor before use if you have

- Trouble urinating due to enlarged prostate gland
- A breathing problem such as emphysema or chronic bronchitis
- Glaucoma

Ask 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 accidental overdose, get medical help or contact a Poison Control Center immediately.

Directions:

- Take every 4-6 hours
- Do not take more than 6 doses in 24 hours.

Adults and children 12 years or over	1 capsule
Children under 12 years	ask a doctor

Other information:

- **Tamper Evident: Do not use if safety seal under cap is broken or missing**
- Store at room temperature 15°-30°C (59°-86°F)
- Protect from moisture
- Use by expiration date on package

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? Adverse drug event call:

(866) 562-2756

PHARBEDRYL

diphenhydramine hcl capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67046-006(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: HBR47K3TBD)	
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:67046-006-30	30 in 1 BLISTER PACK; Type 0: Not a Combination Product	09/11/2017	

Marketing Information

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

Labeler - Contract Pharmacy Services-PA (945429777)

Establishment

Name	Address	ID/FEI	Business Operations
Coupler Enterprises		945429777	repack(67046-006)

Revised: 9/2017

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