

## **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.*

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### **Diphenhydramine 25 mg Capsule #30 007**

#### **Drug Facts**

#### **Active ingredient(in each banded capsule)**

Diphenhydramine HCL 25 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 or pharmacist 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 accidental overdose, get medical help or contact a Poison Control Center immediately.

**Directions:**

- Take every 4-6 hours
- Do not exceed 6 doses in 24 hours.

Adults and children 12 years of age or over	25 mg to 50 mg (1 to 2 capsules)
Children 6 to under 12 years of age	12.5 mg** to 25 mg (1 capsule)
Children under 6 years	ask a doctor

\*\*12.5 mg dosage strength is not available in this package.

Do not attempt to break capsule.

**Other information:**

- **Tamper Evident: Do not use if safety seal under cap is broken or missing**
- Store at controlled 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**

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## PHARBEDRYL

diphenhydramine hcl capsule

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:67046-007(NDC:16103-348)
<b>Route of Administration</b>	ORAL		

### 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
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**

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

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67046-007-30	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(67046-007)

Revised: 9/2017

Contract Pharmacy Services-PA