

## **LEADER ALLERGY - diphenhydramine hydrochloride capsule**

### **Cardinal Health**

*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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### **Leader Allergy Capsules Drug Facts**

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

Diphenhydramine hydrochloride 25 mg

#### **Purpose**

Antihistamine

#### **Uses**

- temporarily relieves these symptoms of the common cold:
  - runny nose
  - sneezing
- temporarily relieves these symptoms due to hay fever or other respiratory allergies:
  - runny nose
  - sneezing
  - itching of the nose or throat
  - 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**

- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- difficulty in urination due to an enlargement of the prostate gland

##### **Ask a doctor or pharmacist before use if you are**

taking tranquilizers or sedatives.

##### **When using this product**

- excitability may occur, especially in children
- drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- use caution when operating machinery or driving a motor vehicle

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, not more than 6 doses in 24 hours

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adults and children 12 years of age and over	take 1 or 2 tablets
children 6 to under 12 years of age	take 1 tablet
children under 6 years of age	consult a doctor
children under 4 years of age	<b>do not use</b>

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**Other information**

- store at room temperature 15°-30°C (59°-86°F) in a dry place
- protect from light
- do not use if red band around capsule is broken or missing

**Inactive ingredients**

DandC Red No. 28, FDandC Blue No. 1, FDandC Red No. 40, gelatin, lactose, and starch.

**Questions or comments?**

\*This product is not manufactured or distributed by McNeil Consumer Healthcare, Division of McNeil-PPC, Inc., owner of the registered trademark Benadryl Allergy Ultratabs.

Distributed by Cardinal Health

Dublin, OH 43017

www.myleader.com 1-800-200-6313

All leader brand products are 100% satisfaction guaranteed or return to place of purchase for a full refund.

**Package/Label Principal Display Panel**

\*Compare Benadryl® Allergy Kaplets active ingredient

Allergy Tablets

Diphenhydramine Hydrochloride 25 mg

Antihistimine

For Allergy Relief

Runny Nose, Sneezing, Itchy Throat, Itchy, watery eyes

24 Capsules

THIS PRODUCT IS PACKAGED IN A CHILD RESISTANT AND TAMPER EVIDENT PACKAGE.  
USE ONLY IF BLISTERS ARE INTACT.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

## Drug Facts

### Active ingredient (in each capsule)

Diphenhydramine HCl 25 mg ..... Antihistamine

### Purpose

**Uses** ■ temporarily relieves these symptoms of the common cold: ■ runny nose ■ sneezing  
■ temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ runny nose  
■ sneezing ■ itching of the nose or throat ■ 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** ■ a breathing problem such as emphysema or chronic bronchitis  
■ glaucoma ■ trouble urinating due to an enlarged prostate gland

**Ask a doctor or pharmacist before use if you are** taking sedatives or tranquilizers.

**When using this product** ■ excitability may occur especially in children ■ marked drowsiness may occur  
■ avoid alcoholic drinks ■ alcohol, sedatives, and tranquilizers may increase drowsiness ■ be careful when operating machinery or driving a motor vehicle

**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, not more than 6 doses in 24 hours

adults and children 12 years of age and over

take 1 or 2 capsules

children 6 to under 12 years of age

take 1 capsule

children under 6 years of age

consult a doctor

children under 4 years of age

do not use

### Other information

■ store at room temperature 15°-30°C (59°-86°F) in a dry place ■ protect from light ■ do not use if red band around capsule is broken or missing

### Inactive ingredients

D&C Red #28, FD&C Blue #1, FD&C Red #40, gelatin, lactose and starch.

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# Allergy Capsules

Diphenhydramine HCl 25 mg  
Antihistamine

24 CAPSULES



NDC 37205-277-62

**LEADER®**

Compare to  
Benadryl® Allergy  
Kapsels®  
active ingredient

# Allergy Capsules

Diphenhydramine HCl 25 mg  
Antihistamine

**For Allergy Relief**

• Runny Nose • Sneezing



• Itchy Throat • Itchy, Watery Eyes



24 CAPSULES

DISTRIBUTED BY CARDINAL HEALTH  
DUBLIN, OHIO 43017  
CIN 1199652  
www.myleader.com 1-800-200-6313

All Leader® Brand Products are  
100% satisfaction guaranteed or return  
to place of purchase for a full refund.

PLD-A  
FC000171



## LEADER ALLERGY

diphenhydramine hydrochloride capsule

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37205-277
Route of Administration	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
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 (UNII: J2B2A4N98G)	
STARCH, CORN (UNII: O8232NY3SJ)	

### Product Characteristics

Color	PINK (clear) , WHITE (clear) , RED (band)	Score	no score
Shape	CAPSULE	Size	14mm
Flavor		Imprint Code	CPC835
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37205-277-62	2 in 1 CARTON		

1		12 in 1 BLISTER PACK		
2	NDC:37205-277-78	1 in 1 CARTON		
2		100 in 1 BOTTLE		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>		<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part341		04/15/1990	

**Labeler** - Cardinal Health (097537435)

Revised: 6/2012

Cardinal Health