

**ALLERGY- diphenhydramine hcl capsule
Cardinal Health (Leader) 49781**

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 25 mg

Purpose

Antihistamine

Uses

- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies
 - sneezing
 - runny nose
 - itchy, watery eyes
 - itching of the nose or throat

Warnings

Do not use

- to make a child sleepy
- with any other product containing diphenhydramine, even one used on skin

Ask a doctor before use if you have

- glaucoma
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers.

When using this product

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

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
- do not take more than 6 doses in 24 hours

adults and children 12 years of age and over	take 1 to 2 capsules
children 6 to under 12 years of age	take 1 capsule
children under 6 years of age	do not use

Other information

- store between 15-30°C (59° to 86°F)
- Protect from light

Inactive ingredients

butylparaben*, D&C red #28, edible black ink, FD&C blue #1, FD&C red #40, FD&C yellow #6*, gelatin, lactose*, lactose monohydrate*, magnesium stearate*, methylparaben*, polysorbate 80*, propylparaben*, purified water*, sodium lauryl sulphate*, starch

*contains one or more of these ingredients

Questions or comments?

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

Principal Display Panel

Compare to Benadryl® Allergy active ingredient**

Allergy Capsules

Diphenhydramine HCl 25 mg

Antihistamine

For allergy relief

Runny nose

Sneezing

Itchy throat

Itchy, watery eyes

Capsules

Each capsule individually banded for your protection

**This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Benadryl®.

**KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.
TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN
OR MISSING OR IF RED BAND AROUND CAPSULE IS BROKEN OR MISSING.**

DISTRIBUTED BY: CARDINAL HEALTH

DUBLIN, OHIO 43047

www.myleader.com

1-800-200-6313

Product Label

0 96295 12750 8
PLD-C75K
FC003088
Lot No.:
Exp. Date:

Drug Facts (continued)
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Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

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Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

Drug Facts
Active ingredient (in each capsule) Diphenhydramine HCl 25 mg.....Antihistamine

Uses
■ temporarily relieves these symptoms due to hay fever or other upper respiratory allergies
■ sneezing
■ itchy, watery eyes
■ runny nose
■ itching of the nose or throat

Warnings
Do not use
■ to make a child sleepy
■ with any other product containing diphenhydramine, even one used on skin
Ask a doctor before use if you have
■ glaucoma
■ trouble urinating due to an enlarged prostate gland
■ a breathing problem such as emphysema or chronic bronchitis

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

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

Purpose Antihistamine

Do not use to make a child sleepy
with any other product containing diphenhydramine, even one used on skin

Ask a doctor before use if you have glaucoma, trouble urinating due to an enlarged prostate gland, a breathing problem such as emphysema or chronic bronchitis

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

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

Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
sneezing, itchy, watery eyes, runny nose, itching of the nose or throat

Do not use: to make a child sleepy, with any other product containing diphenhydramine, even one used on skin

Ask a doctor or pharmacist before use if you have: glaucoma, trouble urinating due to an enlarged prostate gland, a breathing problem such as emphysema or chronic bronchitis

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Excitability may occur, especially in children

Warnings and Product Information:
All Leader® Brand Products are 100% satisfaction guaranteed or return to place of purchase for a full refund.
TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL, UNDER CAP IS BROKEN OR MISSING OR IF FRED BAND AROUND CAPSULE IS BROKEN OR MISSING.
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DISTRIBUTED BY: CARDINAL HEALTH
DUBLIN, OHIO 43017
CIN 5201413 Rev. 12/15
www.myleader.com
1-800-200-6313

NDC 49781-147-51
LEADER®
Allergy Capsules
Diphenhydramine HCl 25 mg Antihistamine
For Allergy Relief
• Runny Nose • Sneezing • Itchy Throat • Itchy, Watery Eyes
100 CAPSULES
Satisfaction Guaranteed
Each capsule individually banded for your protection
Compare to Benadryl active ingredient

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COATING FREE AREA
9 0 4 9 2 5

Leader Allergy Capsules

ALLERGY

diphenhydramine hcl capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49781-147
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
BUTYLPARABEN (UNII: 3QP1IU3FV8)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	WHITE, PINK	Score	no score
Shape	CAPSULE	Size	14mm
Flavor		Imprint Code	CPC835;DH;25
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49781-147-24	1 in 1 BOX	01/31/2016	12/31/2021
1		24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:49781-147-51	1 in 1 BOX	01/31/2016	12/31/2021

2

100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	01/31/2016	12/31/2021

Labeler - Cardinal Health (Leader) 49781 (097537435)

Revised: 11/2019

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