

DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine hydrochloride capsule
CVS Pharmacy, 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.

0835 - CVS

Drug Facts

Active ingredient (in each banded capsule)

Diphenhydramine HCl 25 mg.

Purpose

Antihistamine

Uses

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

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

- 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

- 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 (1-800-222-1222) 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	1 to 2 capsules
children 6 to under 12 years of age	1 capsule
children under 6 years of age	do not use this product in children under 6 years of age

Other information

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F) □
- protect from moisture □
- see end flap for expiration date and lot number

Inactive ingredients

D&C red #28, FD&C blue #1, FD&C red #40, gelatin, lactose and starch

Questions or comments?

1-800-231-4670

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING OR IF RED BAND AROUND CAPSULE IS BROKEN OR MISSING.

RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION

*This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., owner of the registered trademark Benadryl®.

Distributed by: CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

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V-34601

CVSHealth

Compare to the active ingredient in Benadryl®*

Allergy Relief

DIPHENHYDRAMINE HYDROCHLORIDE,

25 mg - Antihistamine

Relief of:

Sneezing, Runny nose,

Itchy, watery eyes, Itchy throat

365 CAPSULES

VALUE SIZE 365 CAPSULES

CVS Health. Compare to the active ingredient in Benadryl®[®] Capsules

Allergy Relief

DIPHENHYDRAMINE HYDROCHLORIDE, 25 mg Antihistamine

Relief of:
Sneezing, Runny nose, Itchy, watery eyes, Itchy throat

365 CAPSULES Actual Size 

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING OR IF RED BAND AROUND CAPSULE IS BROKEN OR MISSING.

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

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

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

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 ■ 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

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V-34601

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**VALUE SIZE
CERTIFICATION**

CAPSULE #4

SHOWN AT CORRECT SIZE

INSIDE OF LABEL

Drug Facts (continued)

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 (1-800-222-1222) right away.

Directions
■ take every 4 to 6 hours ■ do not take more than 6 doses in 24 hours

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Questions or comments? 1-800-231-4670

DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-825
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)	
GELATIN (UNII: 2G86QN327L)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	pink (Half pink and Half clear with white powder inside)	Score	no score
Shape	CAPSULE	Size	14mm
Flavor		Imprint Code	CPC;835
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-825-00	2 in 1 CARTON	06/20/2018	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:69842-825-22	4 in 1 CARTON	06/20/2018	
2		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:69842-825-12	1 in 1 CARTON	06/20/2018	
3		100 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:69842-825-51	365 in 1 BOTTLE; Type 0: Not a Combination Product	06/20/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/20/2018	

Labeler - CVS Pharmacy, Inc. (062312574)