

**ALLERGY RELIEF DYE-FREE SOFTGEL- diphenhydramine hydrochloride capsule, liquid filled**  
**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.*

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**Allergy Relief Dye-Free Softgel**

***Drug Facts***

***Active ingredients (in each softgel)***

Diphenhydramine HCl 25 mg

***Purpose***

Antihistamine

***Uses***

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose • itchy, watery eyes
- sneezing • 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 • difficulty in urination due to enlargement to the 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 beverages
- alcohol, sedatives, and tranquilizers may increase drowsiness
- use caution 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.**

**Overdose warning:** In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as children even if you do not notice any signs or symptoms.

### ***Directions***

- take every 4 to 6 hours, or as directed by a doctor
- do not take more than 6 doses in 24 hours

adults and children 12 years and older	1 to 2 softgels
children 6 to under 12 years	1 softgel
children 6 under years	do not use

### ***Other information***

- store at 25°C (77°F) in a dry place
- protect from light, heat and moisture

### ***Inactive ingredients***

gelatin, glycerin, isopropyl alcohol, medium chain triglycerides, polyethylene glycol, povidone, purified water, sorbitol sorbitan solution, white ink

### ***Questions or comments?***

**1-888-577-8033** Monday-Friday 9am-4:30pm EST

Compare to the active ingredients in Benadryl® Dye-Free Allergy LIQUID-GELS®\*

### **RELIEF OF:**

- SNEEZING
- RUNNY NOSE
- ITCHY, WATERY EYES
- ITCHY THROAT

### **READ AND KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION**

\*This product is not manufactured or distributed by Johnson&Johnson Corporation, owner of the registered trademark Benadryl® Dye-Free Allergy LIQUID GELS®

Product of UAE

Packaged and Quality Assured in the USA

**TAMPER EVIDENT: DO NOT USE IF BLISTER UNIT IS TORN, BROKEN OR SHOWS SIGNS OF TAMPERING**

**Distributed by: CVS Pharmacy, Inc.** One CVS Drive, Woonsocket, RI 02895





## DRUG FACTS LABEL

### Drug Facts

#### Active ingredient (in each softgel)

Diphenhydramine HCl 25 mg.....Antihistamine

#### Purpose

#### Uses

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose      ■itchy, watery eyes
  - sneezing      ■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
- difficulty in urination due to enlargement of the prostate gland

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### Drug Facts (continued)

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**Overdose warning:** In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as children even if you do not notice any signs or symptoms.

#### Directions

- take every 4 to 6 hours, or as directed by a doctor
- do not take more than 6 doses in 24 hours

adults and children 12 years and older	1 to 2 softgels
children 6 to under 12 years	1 softgel
children under 6 years	do not use

#### Other information

- store at 25°C (77°F) in a dry place
- protect from light, heat and moisture

**Inactive ingredients** edible white ink, gelatin, glycerin, isopropyl alcohol, medium chain triglycerides, polyethylene glycol, povidone, purified water, sorbitol sorbitan solution

#### Questions or comments?

1-888-577-8033 Monday-Friday 8am-4pm EST

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## ALLERGY RELIEF DYE-FREE SOFTGEL

diphenhydramine hydrochloride capsule, liquid filled

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51316-998	
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	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)				
GLYCERIN (UNII: PDC6A3C0OX)				
ISOPROPYL ALCOHOL (UNII: ND2M416302)				
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)				
WATER (UNII: 059QF0KO0R)				
SORBITOL (UNII: 506T60A25R)				
SORBITAN (UNII: 6O92ICV9RU)				
Product Characteristics				
Color	white (Clear Transparent)	Score	no score	
Shape	OVAL	Size	15mm	
Flavor		Imprint Code	780	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316-998-22	2 in 1 CARTON	07/20/2021	
1		12 in 1 BLISTER PACK; 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	07/20/2021	

**Labeler** - CVS PHARMACY, INC (062312574)

