# ALLERGY RELIEF- diphenhydramine hydrochloride capsule TopCo Associates LLC

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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1113 - TCR -2018-0515

**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:
  - 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

- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- 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 right away (1-800-222-1222).

#### **Directions**

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

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

#### Other information

- store between 20-25°C (68-77°F)
- retain carton for complete product information

#### **Inactive ingredients**

benzyl alcohol, butylparaben, D&C red #28, edible black ink, FD&C blue #1, FD&C red #40, gelatin, lactose, magnesium stearate, methylparaben, polysorbate 80, propylparaben, sodium lauryl sulfate

#### PRINCIPAL DISPLAY PANEL

NDC 36800-910-01

TopCare® Health™

Compare to Benadryl® Allergy Active Ingredient\*

Allergy Relief

Diphenhydramine HCl 25 mg

**Antihistamine** 

Relief of:

Sneezing

Itchy, watery eyes

Runny Nose

**Itchy Throat** 

Pharmacists Recommend



# Allergy Relief

24 CAPSULES

DIPHENHYDRAMINE HCI 25 mg - ANTIHISTAMINE

This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Benadryl<sup>®</sup> Allergy.

DO NOT USE IF BLISTER UNITS ARE TORN OR BROKEN OR BAND AROUND ANY CAPSULE IS BROKEN OR MISSING

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TOPCO ASSOCIATES LLC
TOPCO ASSOCIATES LLC
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Scan here for more information or call 1-888-423-0139



magnesium stearate, methylparaben, polysorbate 80, propylparaben, sodium lauryl sulfate benzyl alcohol, butylparaben, D&C red #28, edible black ink, FD&C blue #1, FD&C red #40, gelatin, lactose, Inactive ingredients retain carton for complete product information ■ store between 20-25°C (68-77°F) Other information esn 10u op cuildren under 6 years 1 capsule children 6 to under 12 years 1 to 2 capsules adults and children 12 years and over ■ take every 4 to 6 hours, or as directed by a doctor ■ do not take more than 6 times in 24 hours Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away If pregnant or breast-feeding, ask a health professional before use. be careful when driving a motor vehicle or operating machinery alcohol, sedatives, and tranquilizers may increase drowsiness excitability may occur, especially in children avoid alcoholic drinks When using this product marked drowsiness may occur Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers a breathing problem such as emphysema or chronic bronchitis trouble urinating due to an enlarged prostate gland ■ diaucoma Ask a doctor before use if you have ■ to make a child sleepy
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# Allergy Relief

DIPHENHYDRAMINE HCI 25 mg - ANTIHISTAMINE 24 CAPSULES



COMPARE TO BENADRYL® ALLERGY ACTIVE INGREDIENT\*

VDC 36800-910-01

# Allergy Relief

DIPHENHYDRAMINE HCI 25 mg - ANTIHISTAMINE

#### **RELIEF OF:**

- Sneezing
- Itchy, Watery Eyes

F111301TCR\_R2

- Runny Nose
- Itchy Throat

# 24 CAPSULES



## **ALLERGY RELIEF**

diphenhydramine hydrochloride capsule

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:36800-910

**Route of Administration** ORAL

### **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients			
Ingredient Name	Strength		
BENZYL ALCOHOL (UNII: LKG8494WBH)			
BUTYLPARABEN (UNII: 3QPI1U3FV8)			
<b>D&amp;C RED NO. 28</b> (UNII: 767IP0Y5NH)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
GELATIN (UNII: 2G86QN327L)			
LACTOSE (UNII: J2B2A4N98G)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
METHYLPARABEN (UNII: A2I8C7HI9T)			
POLYSORBATE 80 (UNII: 60ZP39ZG8H)			
PROPYLPARABEN (UNII: Z8IX2SC10H)			
SODIUM LAURYL SULFATE (UNII: 368GB5141J)			

Product Characteristics			
Color	pink, white	Score	no score
Shape	OVAL	Size	14mm
Flavor		Imprint Code	A;20
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:36800- 910-01	2 in 1 CARTON	08/30/2011		
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product			
2	NDC:36800- 910-02	4 in 1 CARTON	08/30/2011		
2		12 in 1 BLISTER PACK; Type 0: Not a Combination Product			
3	NDC:36800- 910-03	1 in 1 CARTON	08/30/2011		
3		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	08/30/2011	

## Labeler - TopCo Associates LLC (006935977)

Revised: 11/2021 TopCo Associates LLC