ALLERGY RELIEF- diphenhydramine hydrochloride capsule Strategic Sourcing Services 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.

HMT - 1113 - 2018-0418

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 62011-0356-1

HealthMart

Compare to Benadryl® Allergy active ingredient

Allergy Relief

Diphenhydramine HCl 25 mg

Antihistamine

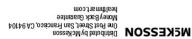
For Relief Of:

Sneezing; Itchy & Watery Eyes

Runny Nose; Itchy Throat

ACTUAL SIZE

100 CAPSULES



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

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

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

> > Drug Facts (continued)

TOO CAPSULES

Antinistamine Diphenhydramine HCI 25 mg





A	esu fon ob	children under 6 years
	ı cəbanle	children 6 to under 12 years
	1 to 2 capsules	adults and children 12 years and over

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

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

Keep out of reach of children. In case of overdose, get medical help or contact a Poison If pregnant or breast-feeding, ask a health professional before use.

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

Drug Facts (continued)



Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers a breathing problem such as emphysema or chronic bronchitis Ask a doctor before use if you have

trouble urinating due to an enlarged prostate gland ■ with any other product containing diphenhydramine, even one used on skin ■ to make a child sleepy Warnings

■ femborsuj\ relieves these symptoms due to the common cold: ■ runny nose ■ sneezing ■ ітсһу, матепу еуез itching of the nose or throat Buizəəus ■ ■ runny nose temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

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Active ingredient (in each capsule) Om 62 DH ənimsəydnədd

Drug Facts



NDC 62011-0356-1

Compare to Benadryl® Allergy active ingredient †

Allergy Relief



Diphenhydramine HCl 25 mg Antihistamine

> For Relief Of: Sneezing; Itchy, Watery Eyes Runny Nose; Itchy Throat

100 CAPSULES

ALLERGY RELIEF

diphenhydramine hydrochloride capsule

Product Information

HUMAN OTC DRUG NDC:62011-0356 **Product Type** Item Code (Source)

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	

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
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)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

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

Packaging				
	# Item Cod	Package Description	Marketing Start Date	Marketing End Date
	NDC:62011- 0356-1	1 in 1 CARTON	03/01/2018	03/31/2025
	1	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	03/01/2018	03/31/2025

Labeler - Strategic Sourcing Services LLC (116956644)

Revised: 11/2022