SHOPRITE ALLERGY RELIEF- diphenhydramine hydrochloride tablet Wakefern Food Corporation

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.

Shoprite Allergy Relief Drug Facts

Active ingredient (in each tablet)

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 of the common cold:
- runny nose
- sneezing

Warnings

Do not use

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

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 (1-800-222-1222).

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 over	1 to 2 tablets
children 6 to under 12 years	1 tablet
children under 6 years	do not use

Other information

- each tablet contains: calcium 20 mg
- store at 20-25°C (68-77°F). Avoid high humidity. Protect from light.
- do not use if blister unit is broken or torn

Inactive ingredients

carnauba wax, crospovidone, D&C red no. 27 aluminum lake, dibasic calcium phosphate dihydrate, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, pregelatinized starch, stearic acid, titanium dioxide

Questions or comments?

1-800-SHOPRITE

Principal Display Panel

Compare to: Active Ingredient in Benadryl® Allergy Ultratabs®

ALLERGY RELIEF

ANTIHISTAMINE

Diphenhydramine HCl 25 mg

Relieves Sneezing, Runny Nose,

Itchy, Watery Eyes, and Itchy Throat

actual size

24 TABLETS



Distributed By: Wakefern Food Corp. 5000 Riverside Drive Keasbey, NJ 08832 @2016

Compare to: Active Ingredient in Benadryl® Allergy Ultratabs®*



ERGY RELIEF

ANTIHISTAMINE

Diphenhydramine HCl 25 mg

Relieves Sneezing, Runny Nose, Itchy, Watery Eyes, and Itchy Throat





å. CS Important: Read a II product information before using . Keep this box for important information.

Drug Facts

Active Ingredient (In each tablet)

Purpose

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- runny noise sneezing itchy, watery eyes itching of the noise or fireat
- temporarily relieves these symptoms due to the common cold: runny nose sneezing

Do notuse ■ to make a child sleepy ■ with any other product containing diphenhy dramine, even one used on skin

Ask a doctor before use if you have

■a breathing problem such as emphysema or chronic bronchifs ■ glaucoma

■ trouble urinating due to an enlarged prostate gland

Ask a doctor or pha im acist before use if you are taking sedatives or tranquilizers

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Directions ■ take every 4 to 6 hours, or as directed by a doc br		■ do not take more than 6 doses in 2.4 h		
adulte and a	hildren 12 years and over	1 to 2 tablets		

adults and children 12 years and over	1 to 2 tablets
children 6 to under 1 2 years	1 tablet
children u nder 6 years	do notuse

Other Information

■ ea ch tab let con tains: calcium 20 mg ■ store at 20-2.5°C (68-7.7°F). Avoid high humidity. Protect from light.

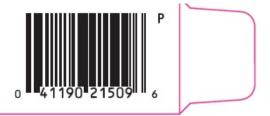
■ do not u se if blister unit is brok en or to m

product is not manufactured or distributed by McNeil Consumer Healthcare, distributor Benadryk® Allergy Ultratabs® Tills

Drug Facts (continued)

Inactive ingredients carnau ba wax, crospovidone, D&C red no. 27 aluminu m lake, dibasic calcium phosphate di hydrate, hypromellose, magnesium stearate, microcrys tall ine cellulose, polyethyl en e gly col, poly sorbate 8 o, pregelatinized starch, stearic acid, titanium dioxide

Questions or comments? 1-800-SHOPRITE



SHOPRITE ALLERGY RELIEF

diphenhydramine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41190-479

Route of Administration ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DIPHENHYDRAMINE HYDRO CHLO RIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg	

Inactive Ingredients	
Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CROSPOVIDONE (15 MPA.S AT 5%) (UNII: 68401960MK)	
D&C RED NO. 27 (UNII: 2LRS 18 5 U 6 K)	
DIBASIC CALCIUM PHO SPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	

Product Characteristics				
Color	PINK (dark)	Score	no score	
Shape	CAPSULE	Size	10 mm	
Flavor		Imprint Code	L479;25	
Contains				

	Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
l	1 NDC:41190-479-62	24 in 1 CARTON	09/22/2016		
	1	1 in 1 BLISTER PACK; Type 0: Not a Combination Product			

2 NDC:41190-479-67	48 in 1 CARTON	09/13/2016		
2	1 in 1 BLISTER PACK; Type 0: Not a Combination Product			
Marketing Information				
war keting iii	or mation			
Marketing Categor	y Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	09/13/2016		

Labeler - Wakefern Food Corporation (069722418)

Revised: 12/2019 Wakefern Food Corporation