# ALLERGY RELIEF- diphenhydramine hcl tablet, chewable WinCo Foods, LLC

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WinCo 44-585 Reserved 67091-425

### Active ingredient (in each chewable tablet)

Diphenhydramine HCl 12.5 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

### 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
- a breathing problem such as emphysema or chronic bronchitis
- difficulty in urination due to enlargement of 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.

In case of overdose, get medical help or contact a Poison Control Center right away.

#### **Directions**

- find right dose on chart below
- chew or crush tablets completely before swallowing; do not swallow tablets whole
- take every 4 to 6 hours, or as directed by a doctor
- do not take more than 6 times in 24 hours

Age (yr)	Dose (chewable tablets)
children under 2 years	do not use
children 2 to 5 years	do not use unless directed by a doctor
children 6 to 11 years	1 to 2 chewable tablets (12.5 mg to 25 mg)
adults and children 12 years and over	2 to 4 chewable tablets (25 mg to 50 mg)

#### Other information

- TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- avoid high humidity
- see end flap for expiration date and lot number

### Inactive ingredients

D&C red #27 aluminum lake, D&C red #30 aluminum lake, dextrates hydrated, ethylcellulose, FD&C blue #1 aluminum lake, flavor, hydroxypropyl cellulose, magnesium stearate, mannitol, stearic acid, sucralose, sucrose

### **Questions?**

Call **1-800-824-1706** Monday – Friday 9am – 4pm MST

### Principal Display Panel

\*Compare to the active ingredient in Children's BENADRYL® Chewables

WinCo® FOODS

Allergy Relief Children's

### DIPHENHYDRAMINE HCI 12.5 mg CHEWABLE TABLETS/ANTIHISTAMINE

Relieves: Sneezing, Runny Nose, Itchy, Watery Eyes & Itchy Throat or Nose

#### 20

Chewable Tablets

CHEW OR CRUSH TABLETS COMPLETELY BEFORE SWALLOWING.

#### **100% SATISFACTION GUARANTEE**

Comments & Questions? www.wincofoods.com

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

#### **DISTRIBUTED BY:**

WINCO FOODS, LLC, BOISE, ID 83704 \* This product is not manufactured or distributed by KENVUE INC., owner of the registered trademark Children's BENADRYL® Chewables.



#### Winco 44-585

#### **ALLERGY RELIEF**

diphenhydramine hcl tablet, chewable

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:67091-425

Route of Administration ORAL

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

Ingredient Name Basis of Strength Strength

**DIPHENHYDRAMINE HYDROCHLORIDE** (UNII: TC2D6IAD40)

(DIPHENHYDRAMINE - UNII:8GTS82S83M)

DIPHENHYDRAMINE HYDROCHLORIDE

12.5 mg

#### **Inactive Ingredients**

D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)

D&C RED NO. 30 ALUMINUM LAKE (UNII: GE75M6YV5W)

DEXTROSE MONOHYDRATE (UNII: LX22YL083G)  ETHYLCELLULOSE, UNSPECIFIED (UNII: 7Z8S9VYZ4B)  FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)  HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)  MAGNESIUM STEARATE (UNII: 70097M6I30)  MANNITOL (UNII: 3OWL53L36A)  STEARIC ACID (UNII: 4ELV7Z65AP)  SUCRALOSE (UNII: 96K6UQ3ZD4)  SUCROSE (UNII: C151H8M554)		
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)  HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)  MAGNESIUM STEARATE (UNII: 70097M6I30)  MANNITOL (UNII: 3OWL53L36A)  STEARIC ACID (UNII: 4ELV7Z65AP)  SUCRALOSE (UNII: 96K6UQ3ZD4)	DEXTROSE MONOHYDRATE (UNII: LX22YL083G)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)  MAGNESIUM STEARATE (UNII: 70097M6I30)  MANNITOL (UNII: 3OWL53L36A)  STEARIC ACID (UNII: 4ELV7Z65AP)  SUCRALOSE (UNII: 96K6UQ3ZD4)	ETHYLCELLULOSE, UNSPECIFIED (UNII: 7Z8S9VYZ4B)	
MAGNESIUM STEARATE (UNII: 70097M6I30)  MANNITOL (UNII: 3OWL53L36A)  STEARIC ACID (UNII: 4ELV7Z65AP)  SUCRALOSE (UNII: 96K6UQ3ZD4)	FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
MANNITOL (UNII: 30WL53L36A) STEARIC ACID (UNII: 4ELV7Z65AP) SUCRALOSE (UNII: 96K6UQ3ZD4)	HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
STEARIC ACID (UNII: 4ELV7Z65AP) SUCRALOSE (UNII: 96K6UQ3ZD4)	MAGNESIUM STEARATE (UNII: 70097M6I30)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	MANNITOL (UNII: 3OWL53L36A)	
	STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCROSE (UNII: C151H8M554)	SUCRALOSE (UNII: 96K6UQ3Z D4)	
	SUCROSE (UNII: C151H8M554)	

Product Characteristics			
Color	purple	Score	no score
Shape	ROUND	Size	12mm
Flavor	GRAPE	Imprint Code	44;585
Contains			

F	Packaging				
#	tem Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:67091-425- 20	4 in 1 CARTON	03/28/2024		
1		5 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 Drug	M012	03/28/2024		

## Labeler - WinCo Foods, LLC (056098817)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		038154464	pack(67091-425)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		832867837	pack(67091-425)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		832867894	manufacture(67091-425)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	pack(67091-425)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		967626305	pack(67091-425)

Revised: 8/2024 WinCo Foods, LLC