

## **CHILDRENS ALLERGY RELIEF- diphenhydramine hcl tablet, chewable**

### **Target 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.*

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### **Target 44-585**

#### **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**

- 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
- 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 (1-800-222-1222) 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

<b>Age (yr)</b>	<b>Dose (chewable tablets)</b>
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, dextrans hydrated, ethylcellulose, FD&C blue #1 aluminum lake, flavor, hydroxypropyl cellulose, magnesium stearate, mannitol, stearic acid, sucralose, sucrose

**Questions?**

**Call 1-800-910-6874**

**Principal display panel**

NDC 11673-985-09

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

**children's  
allergy relief**

diphenhydramine HCl, 12.5 mg chewable tablets  
antihistamine

**relieves:**

- sneezing
- itchy, watery eyes
- runny nose
- itchy throat or nose

chew or crush tablets completely  
before swallowing.

**up&up™**

20 CHEWABLE TABLETS

GRAPE FLAVOR

ACTUAL SIZE

CHEWABLE TABLETS

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

Dist. by Target Corporation  
Minneapolis, MN 55403  
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distributed by Johnson & Johnson  
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trademark Children's Benadryl®  
Chewables.

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Target 44-585

CHILDRENS ALLERGY RELIEF			
diphenhydramine hcl tablet, chewable			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11673-985
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)		DIPHENHYDRAMINE HYDROCHLORIDE	12.5 mg
Inactive Ingredients			
Ingredient Name			Strength
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)			
D&C RED NO. 30 (UNII: 2S42T2808B)			

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

### Product Characteristics

<b>Color</b>	purple	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	12mm
<b>Flavor</b>	GRAPE	<b>Imprint Code</b>	44;585
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11673-985-09	4 in 1 CARTON	04/01/2019	
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 final	part341	04/01/2019	

**Labeler** - Target Corporation (006961700)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(11673-985)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	pack(11673-985)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(11673-985)

### Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LNK International, Inc.		868734088	pack(11673-985)

## **Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LNK International, Inc.		967626305	pack(11673-985)

Revised: 1/2023

Target Corporation