

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

**CVS Pharmacy**

*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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**CVS 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**

- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- 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

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 or comments?**

**1-800-426-9391**

**Principal Display Panel**

**♥CVS Health™**

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

**Chewable Tablets****Children's  
Allergy Relief**

DIPHENHYDRAMINE  
HYDROCHLORIDE, 12.5 mg  
CHEWABLE TABLETS  
Antihistamine

**Relief of:**

- Sneezing
- Runny nose

- Itchy, watery eyes
- Itchy throat

Actual Size

**Grape Flavored**

Child-Resistant Packaging

**18 CHEWABLE TABLETS**

Chew or crush tablets completely before swallowing.

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

\*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Children's Benadryl® Chewables.

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**Distributed by: CVS Pharmacy, Inc.**

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Money Back Guarantee



CVS 44-585

## CHILDRENS ALLERGY RELIEF

diphenhydramine hcl tablet, chewable

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-585
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 (UNII: 2LRS185U6K)	

D&C RED NO. 30 (UNII: 2S42T2808B)	
DEXTROSE MONOHYDRATE (UNII: LX22YL083G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SUCROSE (UNII: C151H8M554)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
ETHYLCELLULOSE, UNSPECIFIED (UNII: 7Z8S9VYZ4B)	

### Product Characteristics

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-585-07	6 in 1 CARTON	03/20/2009	
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:59779-585-44	3 in 1 CARTON	03/20/2009	
2		6 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	03/20/2009	

**Labeler** - CVS Pharmacy (062312574)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(59779-585)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(59779-585)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(59779-585)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(59779-585)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(59779-585)