

CHILDRENS ALLERGY RELIEF- diphenhydramine hcl tablet, chewable
CVS Pharmacy

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 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°C-30°C (59°F-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 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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REV1218D58544

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CVS Health

Children's Allergy Relief
DIPHENHYDRAMINE HYDROCHLORIDE, 12.5 mg CHEWABLE TABLETS, Antihistamine

Chewable Tablets

Drug Facts KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Active ingredient (in each chewable tablet) **Purpose**
Diphenhydramine HCl 12.5 mg 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 ■ alcohol, sedatives, and tranquilizers may increase drowsiness ■ use caution when driving a motor vehicle or operating machinery ■ excitability may occur, especially in children ■ avoid alcoholic beverages
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

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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 UNIT IS TORN, BROKEN OR SHOWS ANY BROKEN
■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
■ see end flap for expiration date and lot number ■ avoid high humidity

Drug Facts (continued)
Inactive ingredients: D&C red #27 aluminum lake, D&C red #90 aluminum lake, decylol, glyceryl stearate, FD&C blue #1 aluminum lake, iron hydroxypropyl cellulose, magnesium stearate, mannitol, stearic acid, sucralose, sucrose
Questions or comments? 1-800-426-9391

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
- Itchy, watery eyes
- Runny nose
- Itchy throat




Actual Size
Grape Flavored
Child-Resistant Packaging

18 CHEWABLE TABLETS

Chew or crush tablets completely before swallowing.

no print / no varnish area
lot no. & exp. date

#483095



0 50428 27426 2

B-0231-585-44-H
REV1218D58544

CVS Health 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 ALUMINUM LAKE (UNII: Z K64F7XSTX)			

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)	

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:59779-585-44	3 in 1 CARTON	03/20/2009	
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:59779-585-07	6 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 Drug	M012	03/20/2009	

Labeler - CVS Pharmacy (062312574)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	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.		832867894	manufacture(59779-585)

Establishment

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

Establishment

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

Revised: 6/2024

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