CHILDRENS ALLERGY RELIEF- diphenhydramine hcl tablet, chewable
Topco Associates, LLC

TopCare 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

- 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

- alcohol, sedatives, and tranquilizers may increase drowsiness
- use caution when driving a motor vehicle or operating machinery
- avoid alcoholic beverages
- marked drowsiness may occur
- 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 25ºC (77ºF); excursions permitted between 15º-30ºC (59º-86ºF)
- 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?

1-888-423-0139

Principal Display Panel

+TopCare®
health

NDC 36800-585-44

COMPARE TO CHILDREN'S BENADRYL® CHEWABLES ACTIVE INGREDIENT*

children's

Allergy Relief

DIPHENHYDRAMINE HCl 12.5 mg
CHEWABLE TABLETS - ANTIHISTAMINE

**4-6
HOURS/
DOSE**

RELIEF OF:

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Nose or Throat

18 CHEWABLE
TABLETS

Chew or crush tablets completely before swallowing.

For Ages 6 to 11 Years

**GRAPE
FLAVOR**

actual size

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.

50844 REV1218B58544

DISTRIBUTED BY
TOPCO ASSOCIATES LLC
ELK GROVE VILLAGE, IL 60007

QUESTIONS? 1-888-423-0139
topcare@topco.com
www.topcarebrand.com

**QUALITY
GUARANTEED**

TopCare health

18 CHEWABLE TABLETS

children's
Allergy Relief

DIPHENHYDRAMINE HCl 12.5 mg
ANTIHISTAMINE

TopCare health

NDC 36800-585-44

COMPARE TO CHILDREN'S BENADRYL® CHEWABLES ACTIVE INGREDIENT*

children's
Allergy Relief
DIPHENHYDRAMINE HCl 12.5 mg
CHEWABLE TABLETS - ANTIHISTAMINE

4-6 HOURS/ DOSE

RELIEF OF:
- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Nose or Throat

18 CHEWABLE TABLETS

Chew or crush tablets completely before swallowing.
For Ages 6 to 11 Years

GRAPE FLAVOR

actual size

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

No Print / No Varnish
Lot no. & Exp. date

0 36800 41435 8

B-1910-585-44-BLR
REV1218B58544

QUALITY GUARANTEED

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

50844 REV1218B58544

DISTRIBUTED BY
TOPCO ASSOCIATES LLC
ELK GROVE VILLAGE, IL 60007
©TOPCO LNK A0521
QUESTIONS? 1-888-423-0139
topcare@topco.com
www.topcarebrand.com

Scan here for more information or call 1-888-423-0139

Drug Facts

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Active ingredient (in each chewable tablet)

Diphenhydramine HCl 12.5 mg ..... Antihistamine

Purpose

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
- alcohol, sedatives, and tranquilizers may increase drowsiness
- use caution when driving a motor vehicle or operating machinery
- avoid alcoholic beverages
- marked drowsiness may occur
- 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.

Drug Facts (continued)

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? 1-888-423-0139

Topcare 44-585

CHILDRENS ALLERGY RELIEF

diphenhydramine hcl tablet, chewable

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:36800-585
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: 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)	

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:36800-585-44	3 in 1 CARTON	03/20/2009	
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
OTC Monograph Drug	M012	03/20/2009	

Labeler - Topco Associates, LLC (006935977)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(36800-585)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	pack(36800-585)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(36800-585)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	pack(36800-585)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(36800-585)

Revised: 7/2024 Topco Associates, LLC