ALLERGY RELIEF CHILDRENS- diphenhydramine hcl tablet, chewable United Natural Foods, Inc. dba UNFI

Equaline 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:
 - itchy, watery eyes
 - runny nose
 - 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
- alcohol, sedatives, and tranquilizers may increase drowsiness
- use caution when driving a motor vehicle or operating machinery
- avoid alcoholic beverages
- 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 or comments?

1-855-423-2630

Principal Display Panel

EQUALINE®

compare to Children's Benadryl® Chewables active ingredient*

NDC 41163-585-44

children's **allergy relief** diphenhydramine HCl 12.5 mg chewable tablets (antihistamine)

for ages 6-11 grape flavor

relieves:

- sneezingitchy throat
- runny nose itchy, watery eyes

18 chewable tablets

actual size

CHEW OR CRUSH TABLETS COMPLETELY BEFORE SWALLOWING. DO NOT SWALLOW TABLETS WHOLE.

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 REV1218C58544

100% Quality GUARANTEED

Like it or let us make it right. **That's our quality promise.** 855-423-2630

DISTRIBUTED BY UNFI PROVIDENCE, RI 02908 USA

EQUALINE®

children's llergy relief

EQUALINE®

children's

lergy relief

diphenhydramine HCl 12.5 mg chewable tablets (antihistamine)

for ages 6-11 grape flavor

compare to Children's Benadryl Chewables

active ingredient* NDC 41163-585-44





actual size

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER Unit is torn, broken or shows any signs of tampering

PROVIDENCE, RI 02908 USA DISTRIBUTED BY UNFI

That's our quality promise. 855-423-2630 Like it or let us make it right.



REV1218058544 Benadry P Chewables.

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

Questions of comments? 1-855-423-2630

Drug Facts (continued)

B-0019E-585-44-F REV1218C58544

9 ∞

S

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

- see end flap for expiration date and lot number
 - avoid high humidity
 - (4.98-.69)
- store at 25°C (77°F); excursions permitted between 15°-30°C OPENED OR BLISTER IS TORN OR BROKEN
 - TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS Other information

2 to 4 chewable tablets (25 mg to 50 mg)	adults and children 12 years and over
to S chevable tablets (fm 2S of gm 5.St)	children 6 to 11 years
do not use unless directed by a doctor	
asu fon ob	children under 2 years
noze (cuewapie rapiers)	(1Y) 9gA

- take every 4 to 6 hours, or as directed by a doctor SWALIOW TABIETS WROLE
- chew or crush tablets completely before swallowing; do not ■ find right dose on chart below DIrections

Drug Facts (continued)

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.

- excitability may occur, especially in children
 - avoid alcoholic beverages
- use caution when driving a motor vehicle or operating machinery ■ slcohol, sedatives, and tranquilizers may increase drowsiness Myeu najud this broduct | marked drowsiness may occur

or tranquilizers.

Ask a doctor or pharmacist before use if you are taking sedatives

- quiticnity in unination due to enlargement of the prostate gland s preathing problem such as emphysema or chronic bronchitis Ask a doctor before use if you have

 glaucoma
 - used on skin

 to make a child sleepy
- with any other product containing diphenhydramine, even one Do not use Warnings

■ runny nose ■ sneezing ■ itching of the nose or throat tever or other upper respiratory allergies:

itchy, watery eyes USes at temporarily relieves these symptoms due to hay

Antihistamine

Purpose

Uphenhydramine HCI 12.5 mg

(in each chewable tablet) Active ingredient

Drug Facts

n 24 hours	do not take more than 6 times in		
Age (yr) Dose (chewable tabl			
asu fon ob	children under 2 years		
do not use unless directed by a doctor			
1 to 2 chewable table (12.5 mg to 25 mg)	children 6 to 11 years		

COMPLETE PRODUCT INFORMATION KEEP OUTER PACKAGE FOR

Equaline 44-585

ALLERGY RELIEF CHILDRENS

diphenhydramine hcl tablet, chewable

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:41163-585

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength		
,,	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)	
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: 30WL53L36A)	
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			

Item Code Package Description Marketing Start Date Marketing End Date 1 NDC:41163-585-44 03/20/2009 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 - United Natural Foods, Inc. dba UNFI (943556183)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(41163-585)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	pack(41163-585)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(41163-585)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	pack(41163-585)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(41163-585)

Revised: 9/2023 United Natural Foods, Inc. dba UNFI