

**ALLERGY RELIEF CHILDRENS- diphenhydramine hcl tablet, chewable
SUPERVALU INC.**

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.

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:
 - 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

- 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
- 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 (1-800-222-1222) right away.

Directions

- find right dose on chart below
- 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

- avoid high humidity
- **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)
- 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?

1-877-932-7948

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
(antihistamine)

for ages 6-11

chewable

grape flavor

relieves:

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

18 tablets

actual size

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

DOES NOT CONTAIN GLUTEN

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

50844 REV0317A58544

**100% Quality
GUARANTEED**

Like it or let us make it right.

That's our quality promise.

877-932-7948

supervaluprivatebrands.com

DISTRIBUTED BY SUPERVALU INC.

EDEN PRAIRIE, MN 55344 USA

EQUALINE®

children's
allergy relief

EQUALINE®

children's
allergy relief

diphenhydramine HCl 12.5 mg
(antihistamine)

for ages 6-11
chewable
grape flavor

relieves:
• sneezing • itchy throat
• runny nose • itchy, watery eyes

18 tablets

compare to
Children's Benadryl®
Chewables
active ingredient*
NDC 41163-585-44



actual size

EQUALINE®

children's
allergy relief

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



B-0019E-585-44-R
REV0317A58544

100% Quality GUARANTEED
That's our quality promise.
Like it or let us make it right.
877-932-7948
superlupivibrabrand.com
DISTRIBUTED BY SUPERVALU INC.
EDEN PRARIE, MN 55344 USA

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

Drug Facts (continued)
Questions or comments? 1-877-932-7948
DOES NOT CONTAIN GLUTEN
*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Children's Benadryl® Chewables.
50844 REV0317A58544

Drug Facts (continued)
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
■ 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 ■ avoid high humidity
■ 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) ■ 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, sucrose, sucrose

Drug Facts
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:
■ 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 OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

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

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:41163-585-44	3 in 1 CARTON	03/20/2009	
1		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 - SUPERVALU INC. (006961411)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	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.		832867837	PACK(41163-585)

Establishment

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

Establishment

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