

**CHILDRENS CHEWABLE ALLERGY RELIEF- diphenhydramine
hydrochloride tablet, chewable
KROGER COMPANY**

**Kroger Diphenhydramine Hydrochloride 12.5 mg Chewable Tablets - Childrens
Grape Flavor**

Drug Facts

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
-sneezing
-itchy, watery eyes
-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
- trouble urinating due to an enlarged 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 alcohol drinks
- alcohol, sedatives and tranquilizers may increase drowsiness
- be careful 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 (1-800-222-1222).

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 (years)	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

- store between 20-25°C (68-77°F). Avoid high humidity. Protect from light.

Inactive ingredients

acacia, crospovidone, D&C red no. 30 aluminum lake, D&C red no. 7, dextrose monohydrate, ethylcellulose, FD&C blue no. 1 aluminum lake, flavors, hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose, sucralose, sucrose, tartaric acid

Questions or comments?

Call **1-800-632-6900**



CHILDRENS CHEWABLE ALLERGY RELIEF

diphenhydramine hydrochloride tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41226-669
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
ACACIA (UNII: 5C5403N26O)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
CROSPVIDONE (UNII: 2S7830E561)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SUCROSE (UNII: C151H8M554)	
DEXTROSE MONOHYDRATE (UNII: LX22YL083G)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
D&C RED NO. 30 ALUMINUM LAKE (UNII: GE75M6YV5W)	
ETHYLCELLULOSE (UNII: 7Z8S9VYZ4B)	

HYDROXYPROPYLCELLULOSE (UNII: 9XZ8H6N6OH)	
MAGNESIUM STEARATE (UNII: 70097M6I3O)	
TARTARIC ACID (UNII: W4888I119H)	

Product Characteristics

Color	purple (Mottled purple color)	Score	no score
Shape	ROUND	Size	13mm
Flavor	GRAPE	Imprint Code	122
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41226-669-02	2 in 1 CARTON	04/30/2025	
1		10 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	04/30/2025	

Labeler - KROGER COMPANY (006999528)

Registrant - TIME CAP LABORATORIES, INC. (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		677604129	manufacture(41226-669)

Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		925822975	manufacture(41226-669)