

CHILDRENS ALLERGY RELIEF- cetirizine hcl tablet, chewable
L.N.K. International, Inc.

Quality Plus 44-578

Active ingredient (in each chewable tablet)

Cetirizine HCl 10 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

if you have ever had an allergic reaction to this product or any of its ingredients or to an antihistamine containing hydroxyzine.

Ask a doctor before use if you have

liver or kidney disease. Your doctor should determine if you need a different dose.

Ask a doctor or pharmacist before use if you are

taking tranquilizers or sedatives.

When using this product

- drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

an allergic reaction to this product occurs. Seek medical help right away.

If pregnant or breast-feeding:

- if breast-feeding: not recommended
- if pregnant: 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

- may be taken with or without water

adults and children 6 years and over	One 10 mg tablet once daily; do not take more than one 10 mg tablet in 24 hours. A 5 mg product may be appropriate for less severe symptoms.
adults 65 years and over	ask a doctor
children under 6 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

Other information

- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- store between 20°-25°C (68°-77°F)
- see end flap for expiration date and lot number

Inactive ingredients

acesulfame potassium, artificial flavors, benzyl alcohol, betadex, colloidal silicon dioxide, dl-alpha-tocopherol, ferric oxide red, ferric oxide yellow, lactose monohydrate, magnesium stearate, maltodextrin, microcrystalline cellulose, propylene glycol, talc, tutti frutti flavor

Questions or comments?

Call 1-800-426-9391 8:30 AM-4:00 PM ET, Monday-Friday

Principal Display Panel

**QUALITY
PLUS**

NDC 50844-578-02

**Compare to the active ingredient
in Children's Zyrtec® Allergy*

AGES 6+

**CHILDREN'S
ALLERGY RELIEF**

Cetirizine HCl Chewable 10 mg
Antihistamine

Indoor and Outdoor Allergies

**Tutti Frutti
Flavored**

12 Chewable 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**

*This product is not manufactured or distributed by McNeil Consumer
Healthcare, owner of the registered trademark Children's Zyrtec® Allergy.
50844 ORG031357802 Product of India

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LNK INTERNATIONAL, INC.
60 Arkay Drive, Hauppauge, NY 11788
USA

AGES 6+ CHILDREN'S ALLERGY RELIEF

NDC 50844-578-02

*Compare to the active ingredient in Children's Zyrtec® Allergy



AGES 6+ CHILDREN'S ALLERGY RELIEF

Cetirizine HCl Chewable 10 mg Antihistamine Indoor and Outdoor Allergies



12 Chewable Tablets

Actual Size

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Drug Facts
 Active ingredient (in each chewable tablet) Cetirizine HCl 10 mg
 Purpose Antihistamine
 Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: sneezing, runny nose, itchy, watery eyes, itching of the nose or throat
 Drug Facts (continued)

Drug Facts (continued)
 Questions or comments? Call 1-800-426-9391 8:30 AM-4:00 PM ET, Monday-Friday
 Distributed by LNK INTERNATIONAL, INC., 60 Arkay Drive, Hauppauge, NY 11788 USA
 Healthcare, owner of the registered trademark Children's Zyrtec® Allergy, 50844 ORG031357802 Product of India

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Drug Facts (continued)

Warnings
 Do not use if you have ever had an allergic reaction to this product or any of its ingredients or to an antihistamine containing hydroxyzine.
 Ask a doctor before use if you have liver or kidney disease, your doctor should determine if you need a different dose.
 Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives.
 When using this product drowsiness may occur alcohol, sedatives, and tranquilizers may increase drowsiness avoid alcoholic drinks be careful when driving a motor vehicle or operating machinery Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.
 If pregnant or breast-feeding: not recommended if pregnant; 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
 may be taken with or without water

Drug Facts (continued)

Other information
 TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN
 store between 20°-25°C (68°-77°F)
 see end flap for expiration date and lot number

Inactive ingredients
 acetylsalicylic acid, artificial flavors, benzyl alcohol, butadiene, colloidal silicon dioxide, d-alpha-tocopherol, ferric oxide red, ferric oxide yellow, lactose monohydrate, magnesium stearate, malto-dextrin, microcrystalline cellulose, polyethylene glycol, talc, tutti frutti flavor

adults and children 6 years and over	One 10 mg tablet once daily. do not take more than one 10 mg tablet in 24 hours. A 5 mg product may be appropriate for less severe symptoms.
adults 6 years and over	ask a doctor
children under 6 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

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Quality Plus 44-578

CHILDRENS ALLERGY RELIEF

cetirizine hcl tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50844-578
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CETIRIZINE HYDROCHLORIDE (UNII: 640047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZINE HYDROCHLORIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BETADEX (UNII: JV039JZZ3A)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TOCOPHERYL NICOTINATE, D-.ALPHA. (UNII: W1J5UCY5C)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	PINK (peach color)	Score	no score
Shape	ROUND	Size	10mm
Flavor	TUTTI FRUTTI	Imprint Code	SZ;106
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50844-578-02	2 in 1 CARTON	10/31/2008	
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
ANDA	ANDA078692	10/31/2008	

Labeler - L.N.K. International, Inc. (038154464)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(50844-578)

Revised: 5/2020

L.N.K. International, Inc.