

ZYRTEC HIVES- cetirizine hydrochloride solution

Kenvue Brands LLC

ZYRTEC Hives

Drug Facts

Active ingredient (in each 5 mL)

Cetirizine HCl 5 mg

Purpose

Antihistamine

Uses

reduces hives and relieves itching due to hives (urticaria). This product will not prevent hives or an allergic skin reaction from occurring.

Warnings

Severe Allergy Warning

Severe Allergy Warning: Get emergency help **immediately** if you have hives along with any of the following symptoms:

- trouble swallowing
- dizziness or loss of consciousness
- swelling of tongue
- swelling in or around mouth
- trouble speaking
- drooling
- wheezing or problems breathing

These symptoms may be signs of anaphylactic shock.

This condition can be life threatening if not treated by a health professional **immediately**. Symptoms of anaphylactic shock may occur when hives first appear or up to a few hours later.

Not a Substitute for Epinephrine. If your doctor has prescribed an epinephrine injector for anaphylaxis or severe allergy symptoms that could occur with your hives, never use this product as a substitute for the epinephrine injector. If you have been prescribed an epinephrine injector, you should carry it with you at all times.

Do not use

- to **prevent** hives from any known cause such as:
 - foods
 - insect stings

■ medicines

■ latex or rubber gloves

because this product will not stop hives from occurring. Avoiding the cause of your hives is the only

way to prevent them. Hives can sometimes be serious. If you do not know the cause of your hives,

see your doctor for a medical exam. Your doctor may be able to help you find a cause.

■ 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.

■ hives that are an unusual color, look bruised or blistered

■ hives that do not itch

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

When using this product

■ drowsiness may occur

■ avoid alcoholic drinks

■ alcohol, sedatives, and tranquilizers may increase drowsiness

■ 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.

■ symptoms do not improve after 3 days of treatment

■ the hives have lasted more than 6 weeks

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

Directions

■ use only with enclosed dosing cup

■ find right dose on chart below

■ mL = milliliter

| | |
|--------------------------------------|--|
| adults and children 6 years and over | 5 mL or 10 mL once daily depending upon severity of symptoms; do not take more than 10 mL in 24 hours. |
| adults 65 years and over | 5 mL once daily; do not take more than 5 mL in 24 hours. |
| children | |

| | |
|--|--------------|
| under 6 years of age | ask a doctor |
| consumers with liver or kidney disease | ask a doctor |

Other information

■ store between 20° to 25°C (68° to 77°F)

■ **do not use if carton is opened or if bottle wrap imprinted with “Sealed For Your Safety” is broken or missing**

Inactive ingredients

Inactive ingredients anhydrous citric acid, flavors, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucralose

Questions?

Questions? call **1-800-343-7805** (toll-free) or **215-273-8755** (collect)

PRINCIPAL DISPLAY PANEL

NDC 50580-128-04

Children’s

ZYRTEC®HIVES

Cetirizine HCl oral solution

1 mg/ml/antihistamine

Hives Relief

6 yrs & old

HIVES RELIEF

24 Hour relief

Reduces Itching Due to Hives

Reduces Hives

Grape Flavor

4 fl oz (118ml)

Dosing cup included



Important: Read all product information before using. Keep this box for important information.

| Drug Facts | Purpose |
|--|---------------|
| Active ingredient (in each 5 mL) Cetirizine HCl 5 mg | Antihistamine |

Uses reduces hives and relieves itching due to hives (urticaria). This product will not prevent hives or an allergic skin reaction from occurring.

Warnings
Severe Allergy Warning: Get emergency help immediately if you have hives along with any of the following symptoms:

- trouble swallowing
- dizziness or loss of consciousness
- swelling of tongue
- swelling in or around mouth
- trouble speaking
- drooling
- wheezing or problems breathing

 These symptoms may be signs of anaphylactic shock. This condition can be life threatening if not treated by a health professional immediately. Symptoms of anaphylactic shock may occur when hives first appear or up to a few hours later.

Not a Substitute for Epinephrine. If your doctor has prescribed an epinephrine injector for "anaphylaxis" or severe allergy symptoms that could occur with your hives, never use this product as a substitute for the epinephrine injector. If you have been prescribed an epinephrine injector, you should carry it with you at all times.

Do not use

- to prevent hives from any known cause such as:
 - foods
 - insect stings
 - medicines
 - latex or rubber gloves
- because this product will not stop hives from occurring. Avoiding the cause of your hives is the only way to prevent them. Hives can sometimes be serious. If you do not know the cause of your hives, see your doctor for a medical exam. Your doctor may be able to help you find a cause.
- 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.
- hives that are an unusual color, look bruised or blistered
- hives that do not itch

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

Drug Facts (continued)

When using this product

- drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- 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.
- symptoms do not improve after 3 days of treatment if the hives have lasted more than 6 weeks

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

Directions

- use only with enclosed dosing cup
- find right dose on chart below
- mL = milliliter

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|--|--|
| adults and children 6 years and over | 5 mL or 10 mL once daily depending upon severity of symptoms; do not take more than 10 mL in 24 hours. |
| adults 65 years and over | 5 mL once daily; do not take more than 5 mL in 24 hours. |
| children under 6 years of age | ask a doctor |
| consumers with liver or kidney disease | ask a doctor |

Other information

- store between 20° to 25°C (68° to 77°F)
- do not use if carton is opened or if bottle wrap imprinted with "Sealed For Your Safety" is broken or missing

Inactive ingredients anhydrous citric acid, flavors, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucralose

Questions? call 1-800-343-7806 (toll-free) or 215-273-8765 (collect).

The trade dress of this ZYRTEC® package is subject to trademark protection. Active ingredient made in Switzerland. Distributed by: KENVUE BRANDS LLC Summit, NJ 07901 © Kenvue Brands LLC 2025 zyrtec.com Pat. www.kenvuepats.com 30059466

Children's ZYRTEC® HIVES
Cetirizine HCl oral solution 1 mg/mL antihistamine
Grape Flavor

NDC 50580-128-04

Children's ZYRTEC® HIVES
Cetirizine HCl oral solution 1 mg/mL antihistamine

Hives Relief
6 yrs & older

HIVES RELIEF

24 Hour relief

Reduces Itching Due to Hives

Reduces Hives

Grape Flavor

4 fl oz (118 mL)

Dosing cup included

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Cetirizine HCl oral solution 1 mg/mL antihistamine

HIVES RELIEF

24 Hour relief

Reduces Itching Due to Hives

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Grape Flavor

4 fl oz (118 mL)

Dosing cup included



ZYRTEC HIVES
cetirizine hydrochloride solution

| Product Information | | | |
|---------------------------------|-----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:50580-128 |
| Route of Administration | ORAL | | |
| Active Ingredient/Active Moiety | | | |
| | Ingredient Name | Basis of Strength | Strength |

| | | |
|---|--------------------------|-----------------|
| CETIRIZINE HYDROCHLORIDE (UNII: 64O047KTOA) (CETIRIZINE - UNII:Y07261ME24) | CETIRIZINE HYDROCHLORIDE | 1 mg in 1 mL |
|---|--------------------------|-----------------|

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| SUCRALOSE (UNII: 96K6UQ3ZD4) | |
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| SORBITOL SOLUTION (UNII: 8KW3E207O2) | |
| WATER (UNII: 059QF0KO0R) | |

Product Characteristics

| | | | |
|-----------------|-------------------|---------------------|--|
| Color | white (COLORLESS) | Score | |
| Shape | | Size | |
| Flavor | GRAPE | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:50580-128-04 | 1 in 1 CARTON | 04/02/2025 | |
| 1 | | 118 mL in 1 BOTTLE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| NDA | NDA022155 | 04/02/2025 | |

Labeler - Kenvue Brands LLC (118772437)

Revised: 6/2025

Kenvue Brands LLC