INDOOR/OUTDOOR ALLERGY RELIEF SOFTGELS- cetirizine hydrochloride capsule CVS Pharmacy

DRUG FACTS

Active Ingredient (in each capsule)

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 reation 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 right away.

Directions

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

Other Information

- store between 20°-25°C (68°-77°F)
- avoid high humidity and excessive heat above 40°C (104°F)
- protect from light

Inactive ingredients

FD&C yellow #6, gelatin, glycerin, mannitol, pharmaceutical ink, polyethylene glycol, purified water, sodium hydroxide, sorbitan, sorbitol

Questions or comments?

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

Principal Display Panel

Compare to the active ingredient in ZYRTEC®*

Original Prescription Strength

24 HOUR Symptom Relief

INDOOR & OUTDOOR ALLERGY RELIEF

CETIRIZINE HYDROCHLORIDE SOFTGELS 10 mg / ANTIHISTAMINE

24 hour relief of:

- Runny nose
- Itchy, watery eyes
- Sneezing
- Itchy throat or nose

Softgels†

†Liquid-filled capsules

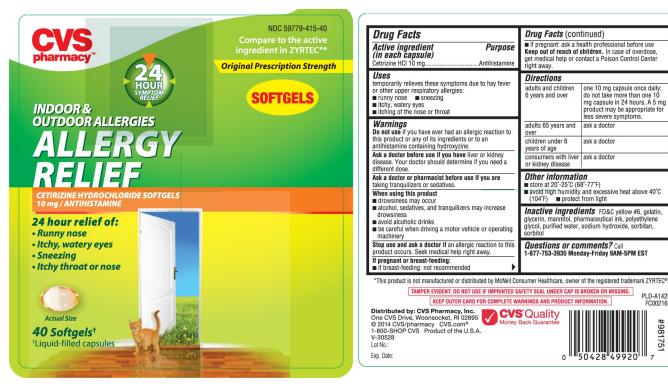
*This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark ZYRTEC®.

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Distributed by: CVS Pharmacy, Inc.

Package Label



CVS Pharmacy Indoor & Outdoor Allergy Relief

INDOOR/OUTDOOR ALLERGY RELIEF SOFTGELS

cetirizine hydrochloride capsule

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:59779-415 |
| Route of Administration | ORAL | | |

| I | Active Ingredient/Active Moiety | | | | |
|---|---|-----------------------------|----------|--|--|
| I | Ingredient Name | Basis of Strength | Strength | | |
| | CETIRIZINE HYDRO CHLO RIDE (UNII: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24) | CETIRIZINE HYDROCHLORIDE | 10 mg | | |

| Inactive Ingredients | | | | |
|---|----------|--|--|--|
| Ingredient Name | Strength | | | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | | | | |
| GELATIN (UNII: 2G86QN327L) | | | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | | |
| MANNITOL (UNII: 3OWL53L36A) | | | | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | | | | |

| WATER (UNII: 059QF0KO0R) | |
|-------------------------------------|--|
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |
| SORBITAN (UNII: 6O92ICV9RU) | |
| SORBITOL (UNII: 506T60A25R) | |

| Product Characteristics | | | |
|-------------------------|---------|--------------|----------|
| Color | YELLOW | Score | no score |
| Shape | CAPSULE | Size | 7mm |
| Flavor | | Imprint Code | CET |
| Contains | | | |

| P | Packaging | | | |
|---|----------------------|--|-------------------------|-----------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:59779-415- 30 | 1 in 1 PACKAGE | 0 3/0 1/20 13 | 12/31/2020 |
| 1 | | 30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |
| 2 | NDC:59779-415- 25 | 1 in 1 PACKAGE | 0 3/0 1/20 13 | 12/31/2020 |
| 2 | | 25 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |
| 3 | NDC:59779-415- 40 | 1 in 1 PACKAGE | 0 3/0 1/20 13 | 12/31/2020 |
| 3 | | 40 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| NDA | NDA022429 | 03/01/2013 | 12/31/2020 |
| | | | |

Labeler - CVS Pharmacy (062312574)

Revised: 12/2018 CVS Pharmacy