CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablet CVS Pharmacy

Drug Facts

ACTIVE INGREDIENT (IN EACH TABLET)

Cetirizine HCl, USP 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
- 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.

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

adults and children 6 one 10 mg tablet once daily; do not take more than one 10 mg tablet in 24 hours.

years and over

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

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

■ TAMPER EVIDENT: DO NOT USE IF BLISTER UNITS ARE TORN, BROKEN OR SHOW ANY SIGNS OF TAMPERING.

INACTIVE INGREDIENTS

Corn starch, hypromellose, lactose monohydrate, magnesium stearate, polyethylene glycol, povidone, talc, titanium dioxide

QUESTIONS?

Call 1-800-406-7984

PRINCIPAL DISPLAY PANEL

CVS[®] pharmacy

Compare to the active ingredient in Zyrtec®*

Original Prescription Strength

INDOOR/OUTDOOR

ALLERGY RELIEF

24 HOUR

CETIRIZINE HYDROCHLORIDE TABLETS, 10 mg

ANTIHISTAMINE

24 hour relief of:

- Sneezing
- Runny nose
- Itchy, watery eyes
- Itching of the nose or throat

5 Tablets 10 mg Each

Distributed by: CVS Pharmacy, Inc.

5087957/0711

1170 Zyrtec® is a registered trademark of UCB Pharma, S.A. *This product is not manufactured or distributed by McNeil-PPC, Inc., distributor of Zyrtec®.









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Antihistamine

Purpose



5 Tablets 10 mg Each

Sneezing

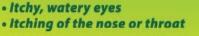
24 hour relief of:

ANTIHISTAMINE

Runny nose

INDOOR/OUTDOOR

- Itchy, watery eyes







Non Varnish Area

one 10 mg tablet once daily; do not take more than one 10 mg tablet in 24 hours.

| Other information | |
|--|---|
| consumers with liver or kidney disease | ask a doctor |
| children under 6 years of age | ask a doctor |
| adults 65 years and over | ask a doctor |
| | A 5 mg product may be appropriate for less severe symptoms. |

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) It pregnant or breast-feeding: If breast-feeding: not recommended It pregnant: ask a health professional before use.

Ask a doctor before use if you have liver or kidney disease. Your doctor should determine if you need a different dose. Do not use if you have ever had an allergic reaction to this product or any of its ingredients or to an antihistamine containing

■ itching of the nose or throat

Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.

■ store between 20° to 25° C (68° to 77° F) ■ TAMPER EVIDENT: DO NOT USE IF BLISTER UNITS ARE TORN, BROKEN OR SHOW ANY SIGNS OF TAMPERING.

Inactive ingredients

When using this product

Drug Facts (continued)

Active ingredient (in each tablet)

Original Prescription Strength

Cetirizine HCI, USP 10 mg

Compare to the active ingredient in Zyrtec**

Drug Facts

corn starch, hypromellose, lactose monohydrate, magnesium stearate, polyethylene glycol, povidone, talc, titanium dioxide

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

■ sneezing ■ itchy, watery eyes

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

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:59779-939

Route of Administration ORAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name
Strength

STARCH, CORN (UNII: 08232NY3SJ)
HYPROMELLOSES (UNII: 3NXW29V3WO)

LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)

MAGNESIUM STEARATE (UNII: 70097M6I30)

POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)

POVIDONE (UNII: FZ989GH94E)

TALC (UNII: 7SEV7J4R1U)

TITANIUM DIO XIDE (UNII: 15FIX9V2JP)

| Product Characteristics | | | |
|-------------------------|-------------------------|--------------|----------|
| Color | white | Score | no score |
| Shape | RECTANGLE (Rounded Off) | Size | 9mm |
| Flavor | | Imprint Code | R152 |
| Contains | | | |

| Packaging | | | | |
|-----------|------------------|----------------------|-----------------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:59779-939-56 | 5 in 1 BLISTER PACK | | |
| 2 | NDC:59779-939-54 | 14 in 1 BLISTER PACK | | |
| 3 | NDC:59779-939-30 | 30 in 1 BOTTLE | | |
| 4 | NDC:59779-939-43 | 45 in 1 BOTTLE | | |
| 5 | NDC:59779-939-90 | 90 in 1 BOTTLE | | |
| 6 | NDC:59779-939-13 | 120 in 1 BOTTLE | | |

| ANDA | ANDA077498 | 12/27/2007 | |
|------|------------|------------|--|
| | | | |

Labeler - CVS Pharmacy (062312574)

Registrant - Ranbaxy Pharmaceuticals Inc. (937890044)

| Establishment | | | | |
|-----------------------|---------|-----------|------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Ohm Laboratories Inc. | | 184769029 | manufacture(59779-939) | |

Revised: 3/2013 CVS Pharmacy