CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablet Proficient Rx LP

Cetirizine Hydrochloride Tablets USP, 10 mg, Allergy

ACTIVE INGREDIENTS

Active Ingredients (in each tablet)

Purpose

Cetirizine HCl USP 10 mg......Antihistimine

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 DOCTOR

Ask a doctor before use if you have liver or kidney disease. Your doctor should determine if you need a different dose.

ASK DOCTOR/PHARMACIST

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

WHEN USING THIS PRODUCT

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

STOP USE

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 Poison Control Center right away.

DIRECTIONS

| Adults and children 6 | one 10 mg tablet once daily, do not take more than |
|--|--|
| years and over | 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

store at 20° to 25°C (68° to 77°F)

[See USP Controlled Room Temperature]

INACTIVE INGREDIENTS

Hypromellose, lactose, magnesium stearate, maize starch, polyethylene glycol, povidone, titanium dioxide.

QUESTIONS?

Call 1-866-562-4597

Manufactured by:

Unique Pharmaceutical Labs.

(A Div. of J. B. Chemicals & Pharmaceuticals Ltd.), Mumbai 400 030, India

Distributed by:

Rising Pharmaceuticals, Inc. Saddle Brook, NJ 07663

M. L. G/1430 May 2018

Repackaged by:

Proficient Rx LP. Thousand Oaks, CA 91320 120005

PRINCIPAL DISPLAY PANEL-30'S COUNT

-PRINCIPAL DISPLAY PANEL----

71205-164-30 Original Prescription Strength Cetirizine Hydrochloride Tablets USP 10 mg 6 yrs & older 30 Tablets





NDC 71205-164-30

Lot #:00000 Exp. 00/00/00 SN# MASTER

Cetirizine HCI 10mg #30 Tablets Lot #:00000 NDC 71205-164-30

SN# MASTER Exp:00/00/00

Cetirizine HCI 10mg

#30 Tablets Lot #:00000 NDC 71205-164-30

SN# MASTER Exp:00/00/00

Cetirizine HCI 10mg #30 Tablets Lot #:00000 NDC 71205-164-30

SN# MASTER Exp:00/00/00

Cetirizine HCI 10mg

#30

Tablets

Each tablet contains: Cetirizine HCI USP 10 mg Antihistamine

White, bullet (barrel shaped), unscored tablet with imprint code CTN and 10.

Product ID: QC016430

Mfr. By: Unique Pharmaceutical Labs, (A Div. of J. B. Chemicals & Pharmaceuticals Ltd.), Mumbai 400 030, India. Store at 20° to 25°C (68° to 77°F) Keep medication out of the reach of children

Packaged By: Proficient Rx LP Thousand Oaks, CA 91320

CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:71205-164(NDC:16571-402)

Route of Administration ORAL

Active Ingredient/Active Moiety

Basis of Strength Ingredient Name Strength Cetirizine Hydrochloride (UNII: 64O047KTOA) (Cetirizine - UNII:YO7261ME24) Cetirizine Hydrochloride 10 mg

| Inactive Ingredients | | |
|---|----------|--|
| Ingredient Name | Strength | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | | |
| LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G) | | |
| magnesium stearate (UNII: 70097M6I30) | | |
| starch, corn (UNII: O8232NY3SJ) | | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | | |
| PO VIDO NE, UNSPECIFIED (UNII: FZ989GH94E) | | |
| titanium dioxide (UNII: 15FIX9V2JP) | | |
| | | |

| Product Characteristics | | | |
|-------------------------|------------------------|--------------|----------|
| Color | WHITE (White) | Score | no score |
| Shape | BULLET (Barrel Shaped) | Size | 8 mm |
| Flavor | | Imprint Code | CTN;10 |
| Contains | | | |

| F | Packaging | | | |
|---|---|---|-----------------------------|---------------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:71205-164-15 | 15 in 1 BOTTLE; Type 0: Not a Combination Product | 12/0 1/20 18 | |
| 2 | 2 NDC:71205-164-30 30 in 1 BOTTLE; Type 0: Not a Combination Product 12 | | 12/0 1/20 18 | |
| 3 | NDC:71205-164-60 | 60 in 1 BOTTLE; Type 0: Not a Combination Product | 12/0 1/20 18 | |
| 4 | NDC:71205-164-90 | 90 in 1 BOTTLE; Type 0: Not a Combination Product | 12/0 1/20 18 | |

| Marketing Information | | | |
|-----------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| ANDA | ANDA077829 | 10/01/2009 | |
| | | | |

Labeler - Proficient Rx LP (079196022)

| Establishment | | | |
|------------------|---------|-----------|---------------------------------------|
| Name | Address | ID/FEI | Business Operations |
| Proficient Rx LP | | 079196022 | REPACK(71205-164), RELABEL(71205-164) |

Revised: 10/2019 Proficient Rx LP