**CETIRIZINE HYDROCHLORIDE (ALLERGY) - cetirizine hydrochloride tablet**
**Aurohealth LLC**

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**Cetirizine Hydrochloride Tablets (Allergy)**

***Drug Facts***

***Active ingredient (in each tablet)***

**For 5 mg:**

Cetirizine hydrochloride USP 5 mg

**For 10 mg:**

Cetirizine hydrochloride 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***

**For 5 mg:**

| | |
|---|---|
| adults and children 6 years and over | 1 tablet (5 mg) or 2 tablets (10 mg) once daily depending upon severity of symptoms; do not take more than 2 tablets (10 mg) in 24 hours. |
| adults 65 years and over | 1 tablet (5 mg) once daily; do not take more than 1 tablet (5 mg) in 24 hours. |
| children under 6 years of age | ask a doctor |
| consumers with liver or kidney disease | ask a doctor |

**For 10 mg:**

| | |
|---|---|
| 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***
- store between 20° to 25°C (68° to 77°F)
- **TAMPER EVIDENT: DO NOT USE IF SEAL OVER BOTTLE OPENING IS BROKEN OR MISSING.**

***Inactive ingredients***

colloidal silicon dioxide, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide.

***Questions?***

call **1-855-274-4122**

Distributed by:
**AUROHEALTH LLC**
279 Princeton-Hightstown,
East Windsor, NJ 08520

Made in India

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 5 mg (30's Tablet Container Carton Label)**

**AUROHEALTH**

**NDC 58602-444-09**

***Compare to the active ingredient of Zyrtec®**

**Original Prescription Strength**

**Allergy Relief**
**Cetirizine Hydrochloride**
**Tablets USP 5 mg**

**Antihistamine**

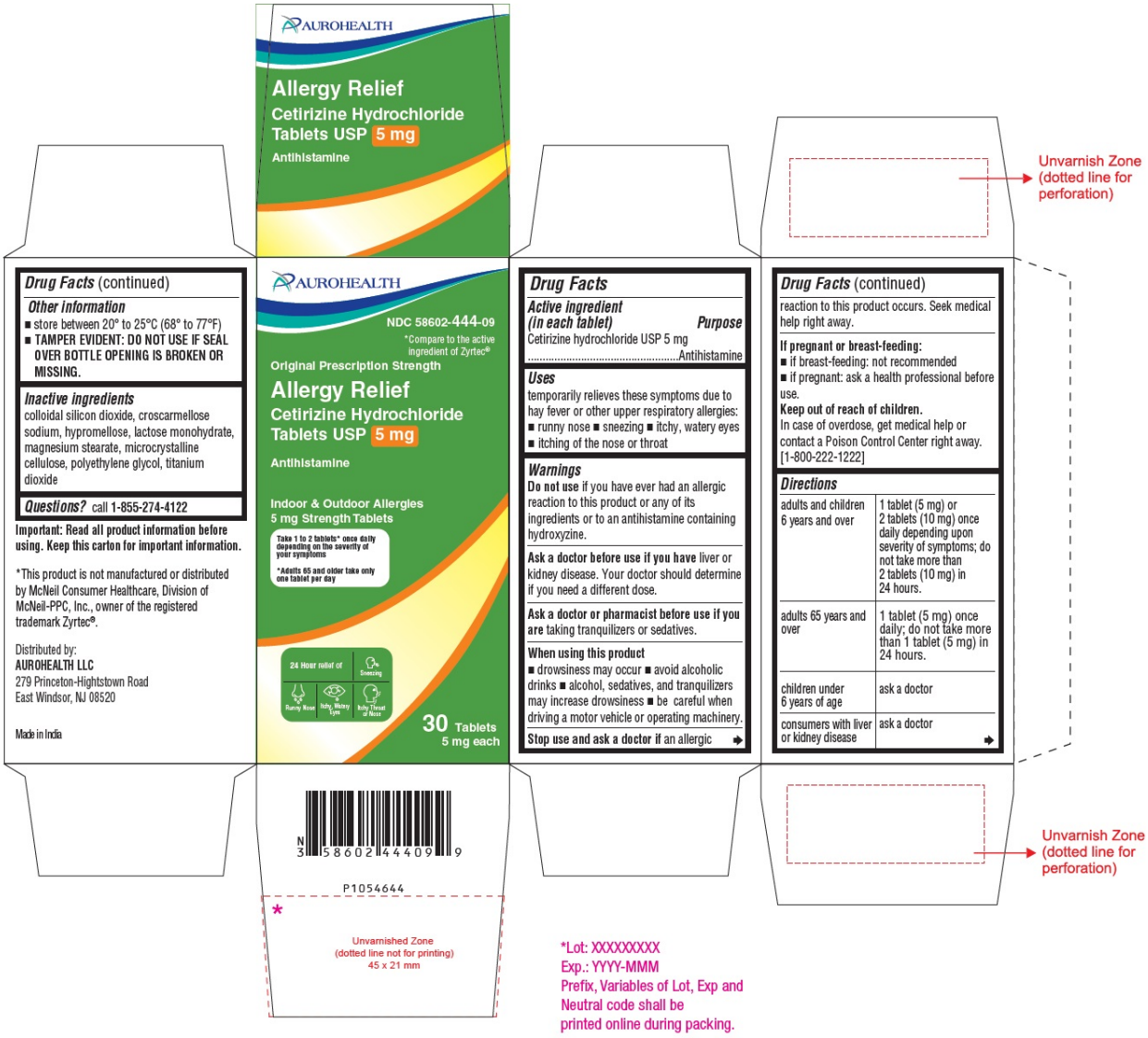
**Indoor & Outdoor Allergies**
**5 mg Strength Tablets**

**Take 1 to 2 tablets* once daily depending on the severity of your symptoms**

***Adults 65 and older take only one tablet per day**

24 Hour relief of
- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Throat or Nose

**30 Tablets**
**5 mg each**




**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL -5 mg (10 x 10 Blister Carton Label)**

**AUROHEALTH**

**NDC 58602-444-21**

***Compare to the active ingredient of Zyrtec®**

**Allergy Relief**
**Cetirizine Hydrochloride Tablets USP 5 mg**
**Antihistamine**
**Original Prescription Strength**

**Indoor & Outdoor Allergies**
**5 mg Strength Tablets**

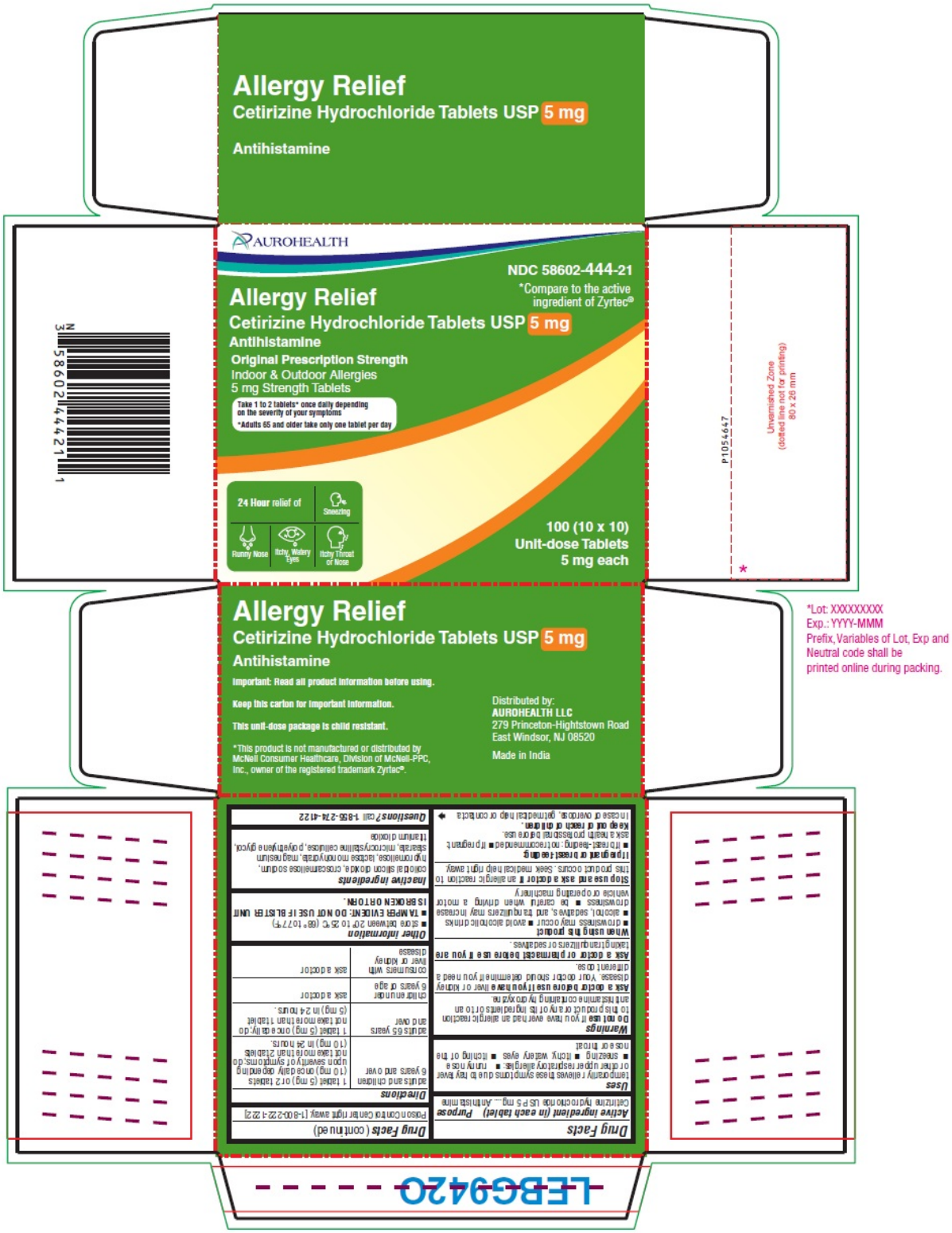
**Take 1 to 2 tablets* once daily depending on the severity of your symptoms**

***Adults 65 and older take only one tablet per day**

24 Hour relief of

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Throat or Nose

**100 (10 x 10)**
**unit-dose Tablets**
**5 mg each**




**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 10 mg (30's Tablet Container Carton Label)**

**AUROHEALTH**

**NDC 58602-445-09**

***Compare to the active ingredient of Zyrtec®**

**Allergy Relief**
**Cetirizine Hydrochloride Tablets USP 10 mg**
**Antihistamine**
**Original Prescription Strength**

**Indoor & Outdoor Allergies**
**10 mg Strength Tablets**

24 Hour relief of

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Throat or Nose

**30 Tablets**
**10 mg each**

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 10 mg (10 x 10 Blister Carton Label)**

**AUROHEALTH**

**NDC 58602-445-21**

***Compare to the active ingredient of Zyrtec®**

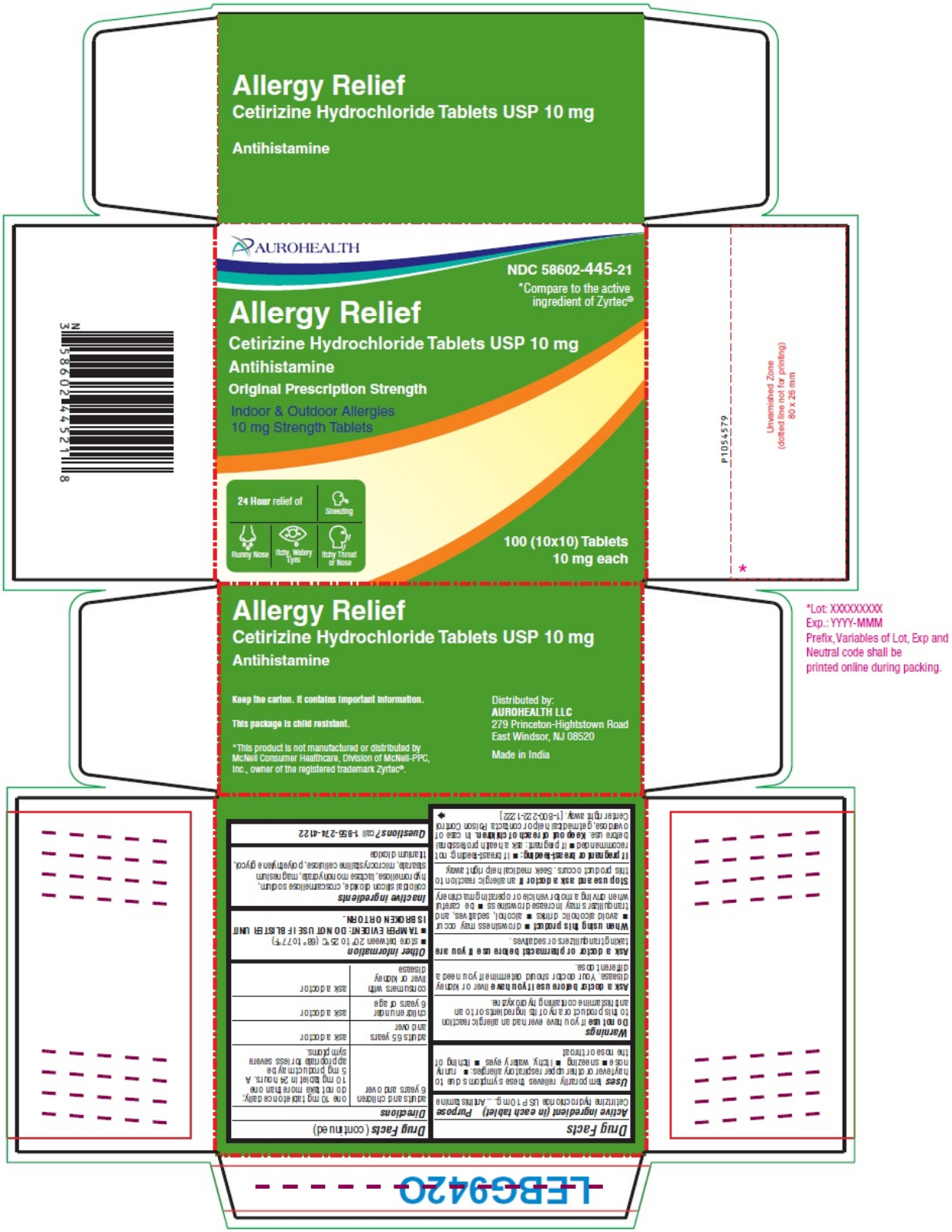
**Allergy Relief**
**Cetirizine Hydrochloride Tablets USP 10 mg**
**Antihistamine**
**Original Prescription Strength**

**Indoor & Outdoor Allergies**
**10 mg Strength Tablets**

24 Hour relief of

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Throat or Nose

**100 (10x10) Tablets**
**10 mg each**



# CETIRIZINE HYDROCHLORIDE (ALLERGY)

cetirizine hydrochloride tablet

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:58602-444 |
| **Route of Administration** | ORAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **CETIRIZINE HYDROCHLORIDE** (UNII: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24) | CETIRIZINE HYDROCHLORIDE | 5 mg |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **CROSCARMELLOSE SODIUM** (UNII: M28OL1HH48) | |
| **HYPROMELLOSE 2910 (5 MPA.S)** (UNII: R75537T0T4) | |
| **LACTOSE MONOHYDRATE** (UNII: EWQ57Q8I5X) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **MICROCRYSTALLINE CELLULOSE** (UNII: OP1R32D61U) | |
| **POLYETHYLENE GLYCOL 400** (UNII: B697894SGQ) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | WHITE (White to Off-white) | **Score** | no score |
| **Shape** | ROUND | **Size** | 6mm |
| **Flavor** | | **Imprint Code** | X;35 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:58602-444-09 | 1 in 1 CARTON | 08/05/2015 | |
| **1** | | 30 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| **2** | NDC:58602-444-17 | 1 in 1 CARTON | 08/05/2015 | |
| **2** | | 45 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| **3** | NDC:58602-444-47 | 75 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product | 08/05/2015 | |
| **4** | NDC:58602-444-41 | 1000 in 1 BOTTLE; Type 0: Not a Combination Product | 08/05/2015 | |
| **5** | NDC:58602-444-21 | 10 in 1 CARTON | 08/05/2015 | |
| **5** | | 10 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 | ANDA090760 | 08/05/2015 | |

# CETIRIZINE HYDROCHLORIDE (ALLERGY)

cetirizine hydrochloride tablet

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:58602-445 |
| **Route of Administration** | ORAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **CETIRIZINE HYDROCHLORIDE** (UNII: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24) | CETIRIZINE HYDROCHLORIDE | 10 mg |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **CROSCARMELLOSE SODIUM** (UNII: M28OL1HH48) | |
| **HYPROMELLOSE 2910 (5 MPA.S)** (UNII: R75537T0T4) | |
| **LACTOSE MONOHYDRATE** (UNII: EWQ57Q8I5X) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **MICROCRYSTALLINE CELLULOSE** (UNII: OP1R32D61U) | |
| **POLYETHYLENE GLYCOL 400** (UNII: B697894SGQ) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | WHITE (White to Off-white) | **Score** | no score |
| **Shape** | ROUND | **Size** | 8mm |
| **Flavor** | | **Imprint Code** | X;36 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:58602-445-09 | 1 in 1 CARTON | 08/05/2015 | |
| **1** | | 30 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| **2** | NDC:58602-445-17 | 1 in 1 CARTON | 08/05/2015 | |
| **2** | | 45 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| **3** | NDC:58602-445-47 | 75 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product | 08/05/2015 | |
| **4** | NDC:58602-445-15 | 1 in 1 CARTON | 08/05/2015 | |
| **4** | | 60 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| **5** | NDC:58602-445-19 | 1 in 1 CARTON | 08/05/2015 | |

| | | | | |
|---|---|---|---|---|
| **5** | | 90 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| **6** | NDC:58602-445-94 | 1 in 1 CARTON | 08/05/2015 | |
| **6** | | 100 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| **7** | NDC:58602-445-38 | 1 in 1 CARTON | 08/05/2015 | |
| **7** | | 300 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| **8** | NDC:58602-445-40 | 500 in 1 BOTTLE; Type 0: Not a Combination Product | 08/05/2015 | |
| **9** | NDC:58602-445-41 | 1000 in 1 BOTTLE; Type 0: Not a Combination Product | 08/05/2015 | |
| **10** | NDC:58602-445-21 | 10 in 1 CARTON | 08/05/2015 | |
| **10** | | 10 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| **11** | NDC:58602-445-01 | 1 in 1 CARTON | 08/05/2015 | |
| **11** | | 14 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| **12** | NDC:58602-445-60 | 1 in 1 CARTON | 08/05/2015 | |
| **12** | | 5 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| **13** | NDC:58602-445-54 | 1 in 1 CARTON | 08/05/2015 | |
| **13** | | 70 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| **14** | NDC:58602-445-65 | 2 in 1 CARTON | 11/21/2019 | |
| **14** | | 7 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 | ANDA090760 | 08/05/2015 | |

# CETIRIZINE HYDROCHLORIDE (ALLERGY)

cetirizine hydrochloride tablet

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:58602-812 |
| **Route of Administration** | ORAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **CETIRIZINE HYDROCHLORIDE** (UNII: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24) | CETIRIZINE HYDROCHLORIDE | 10 mg |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **CROSCARMELLOSE SODIUM** (UNII: M28OL1HH48) | |
| **HYPROMELLOSE 2910 (5 MPA.S)** (UNII: R75537T0T4) | |

| | |
|---|---|
| **LACTOSE MONOHYDRATE** (UNII: EWQ57Q8I5X) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **MICROCRYSTALLINE CELLULOSE** (UNII: OP1R32D61U) | |
| **POLYETHYLENE GLYCOL 400** (UNII: B697894SGQ) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | WHITE (White to Off-white) | **Score** | 2 pieces |
| **Shape** | RECTANGLE (off-rectangular) | **Size** | 9mm |
| **Flavor** | | **Imprint Code** | X;2;0 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:58602-812-09 | 1 in 1 CARTON | 08/05/2015 | |
| **1** | | 30 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| **2** | NDC:58602-812-17 | 1 in 1 CARTON | 08/05/2015 | |
| **2** | | 45 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| **3** | NDC:58602-812-99 | 75 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product | 08/05/2015 | |
| **4** | NDC:58602-812-23 | 1 in 1 CARTON | 08/05/2015 | |
| **4** | | 120 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| **5** | NDC:58602-812-39 | 1 in 1 CARTON | 08/05/2015 | |
| **5** | | 365 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| **6** | NDC:58602-812-41 | 1000 in 1 BOTTLE; Type 0: Not a Combination Product | 08/05/2015 | |
| **7** | NDC:58602-812-04 | 10 in 1 CARTON | 08/05/2015 | |
| **7** | NDC:58602-812-83 | 10 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 | ANDA090760 | 08/05/2015 | |

## Labeler - Aurohealth LLC (078728447)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| APL HEALTHCARE LIMITED | | 650844777 | ANALYSIS(58602-444, 58602-445, 58602-812) , MANUFACTURE(58602-444, 58602-445, 58602-812) |

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Aurobindo Pharma Limited | | 918917642 | ANALYSIS(58602-444, 58602-445, 58602-812) , MANUFACTURE(58602-444, 58602-445, 58602-812) |