**CETIRIZINE HYDROCHLORIDE - cetirizine hydrochloride tablet, film coated**
**Indoco Remedies Limited**

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**Cetirizine Tablets 10 mg**
***Drugs Facts***

**ACTIVE INGREDIENT(S)**

Cetirizine HCl 10 mg

**PURPOSE**

Antihistamine

**USE(S)**

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**

**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 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)
- **do not use if foil inner seal is broken or missing**
- FDA approved dissolution test specifications differ from USP

**Inactive ingredients**

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

**Questions?**

Call at **+1-855-642-2594**

**PRINCIPAL DISPLAY PANEL**

Original Prescription Strength

NDC 14445-152-30

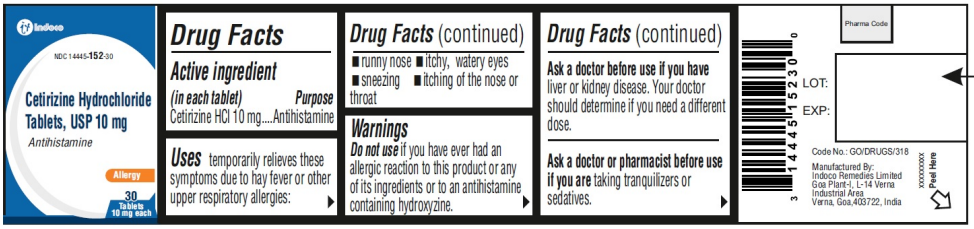
Cetirizine Hydrochloride Tablets
ALLERGY

Cetirizine HCl tablets
10 mg /antihistamine

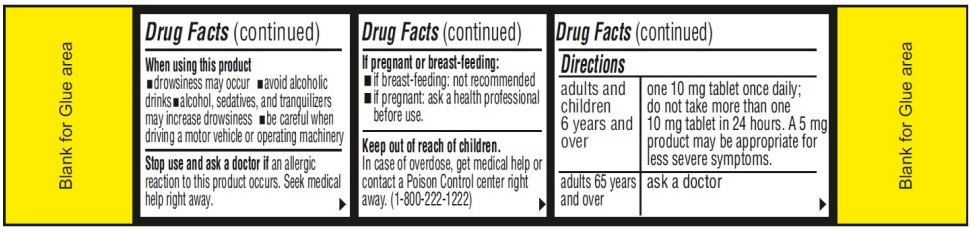
Indoor & Outdoor Allergies

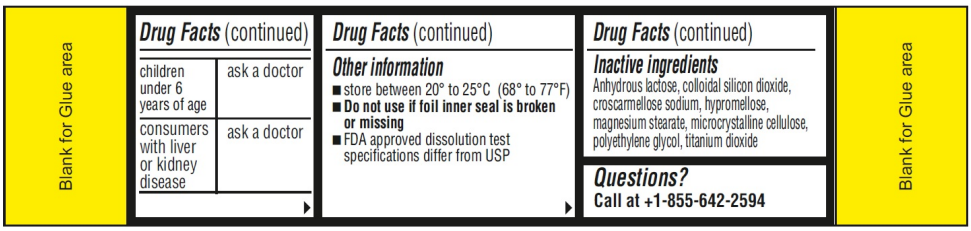
24 hour Relief of
• runny nose
• sneezing
• itchy, watery eyes
• itchy throat or nose
30 Tablets
10 mg each

Container Label:

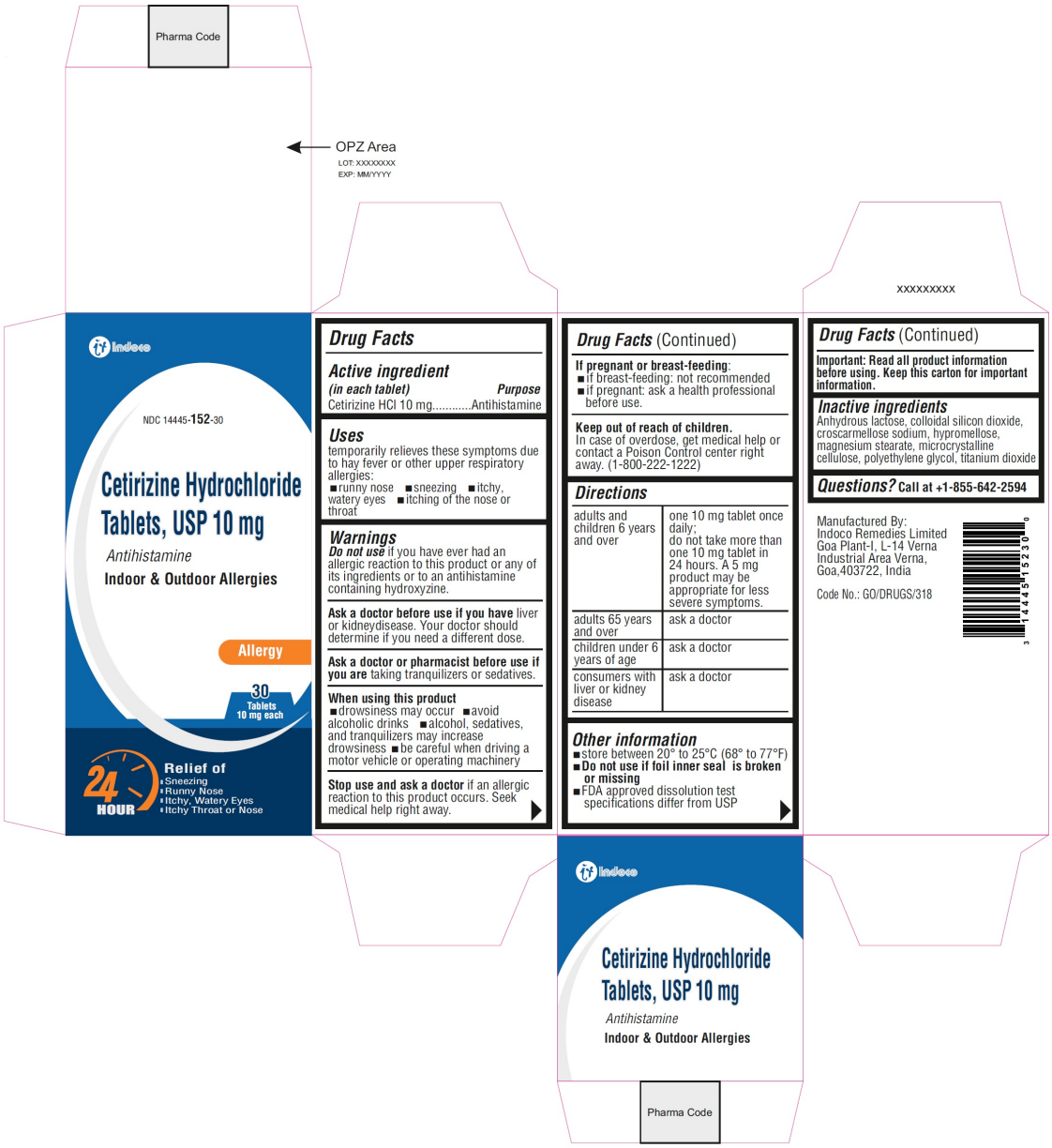



← OPZ Area
15 x 10 mm
LOT: xxxxxxxx
EXP: YYYY-MM




Carton Label:




# CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet, film coated

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:14445-152 |
| **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 |
|---|---|
| **ANHYDROUS LACTOSE** (UNII: 3SY5LH9PMK) | |
| **CELLULOSE, MICROCRYSTALLINE** (UNII: OP1R32D61U) | |
| **CROSCARMELLOSE SODIUM** (UNII: M28OL1HH48) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **HYPROMELLOSE 2910 (6 MPA.S)** (UNII: 0WZ8WG20P6) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **POLYETHYLENE GLYCOL 400** (UNII: B697894SGQ) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | WHITE | **Score** | 2 pieces |
| **Shape** | CAPSULE | **Size** | 9mm |
| **Flavor** | | **Imprint Code** | C10 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:14445-152-30 | 1 in 1 CARTON | 10/04/2024 | |
| **1** | | 30 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| **2** | NDC:14445-152-90 | 1 in 1 CARTON | 10/04/2024 | |
| **2** | | 90 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| **3** | NDC:14445-152-01 | 1 in 1 CARTON | 10/04/2024 | |
| **3** | | 100 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| **4** | NDC:14445-152-03 | 1 in 1 CARTON | 10/04/2024 | |
| **4** | | 300 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| **5** | NDC:14445-152-05 | 1 in 1 CARTON | 10/04/2024 | |
| **5** | | 500 in 1 BOTTLE; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| ANDA | ANDA218895 | 10/04/2024 | |

## Labeler - Indoco Remedies Limited (650445950)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| INDOCO REMEDIES LIMITED | | 918608431 | ANALYSIS(14445-152) , LABEL(14445-152) , MANUFACTURE(14445-152) , PACK(14445-152) |

Revised: 10/2024 Indoco Remedies Limited